No.

IN THE
Supreme Court of the United States

CIMZNHCA, LLC,
Petitioner,

v.

UNITED STATES OF AMERICA
Respondent,

UCB, INC., *et al.,*
Defendants.

On Appeal from The United States Court of Appeals for the Seventh Circuit
Case No. 19-2273

Cimznhca, LLC's Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

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PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED FOR REVIEW

1. Whether the Seventh Circuit Court of Appeals erroneously exercised jurisdiction over a non-final order by creating a motion to intervene when the Government specifically chose not to intervene as a party and never filed a motion to intervene;
2. Whether the Seventh Circuit erroneously applied and analyzed a good-cause analysis that was never argued or ruled upon in the district court; and
3. Whether the Seventh Circuit's holding violates fundamental principles of procedural due process.

LIST OF PARTIES AND RELATED CASES

All Parties to this action are identified in the case caption.

- *United States of America, et al., ex rel. Cimznhca, LLC. v. UCB, Inc., RXC Acquisition Company d/b/a RX Crossroads, Omnicare, Inc., and CVS Health Corporation*, In the United States District Court for the Southern District of Illinois. Judgment entered June 7, 2019.
- *United States of America v. Cimznhca, LLC., et al.*, No. 19-2273, United States Supreme Court for the Seventh Circuit. Judgment entered August 17, 2020.

CORPORATE DISCLOSURE STATEMENT

The undersigned counsel for Petitioner furnishes the following list in compliance with Rule 29.6:

1. The full name of every party or amicus the attorney represents in the case: CIMZNHCA, LLC

2. Identify all parent corporations: Venari Partners, LLC; 110 Partners, LLC; Min- Fam-Holding, LLC; Sweetbriar Capital, LLC; Uptown Investors, L.P.

3. There is no publicly held company that owns 10% or more of the party's or amicus' stock.

4. The names of all law firms whose partners or associates have appeared for the parties or are expected to appear for the parties in the case: Beasley, Allen, Crow, Methvin, Portis & Miles, P.C. and Quantum Legal LLC

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PETITION FOR WRIT OF CERTIORARI

Cimznhca, LLC petitions this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Seventh Circuit.

OPINIONS AND ORDERS BELOW

The opinion for the United States District Court is reported at Docket 101. The opinion for the Seventh Circuit Court of Appeals is located at Docket 43. The slip copy opinion for the United States District Court for the Southern District of Illinois is located at 019 WL 1598109, Med & Med GD (CCH) P 306,484. The opinion for the Seventh Circuit Court of Appeals is reported at 970 F.3d 835.

STATEMENT OF JURISDICTION

The Seventh Circuit entered judgment on August 17, 2020 and denied Petitioner's timely request for rehearing on September 17, 2020. This Court issued an order on March 19, 2020 extending the deadline to file any petition for writ of certiorari from 90 days to 150 days, and

this Petition is timely filed. The Court has jurisdiction under 28 U.S.C. §1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

U.S. Const. amend V

28 U.S.C. § 1291

31 U.S.C. § 3730(c)(2)(A)

STATEMENT OF THE CASE

In July 2017, Petitioner Relator ("Relator") brought this action under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and corresponding state statutes against UCB, Inc., RXC Acquisition Company, Omnicare Inc., and CVS Health Corporation's ("Defendants") for their improper scheme of providing kickbacks to physicians in exchange for prescriptions for brand-name Cimzia over competitors.

On December 14, 2017, the United States Department of Justice ("Government") chose not to intervene in the litigation. The case was unsealed, and

Relator chose to continue pursuing the case as the FCA expressly allows. More than a year after unequivocally declining to intervene, in December 2018, the Government suddenly filed a motion to dismiss the litigation entirely pursuant to 31 U.S.C. § 3730(c)(2)(A). Interestingly, and most concerning, the Government argued that the claims should be dismissed with prejudice to Relator but not to itself.

The district court conducted an extremely thorough hearing after reviewing briefs on the Government's motion to dismiss. The district court analyzed competing standards and adopted the rational-basis-type review first outlined by the Ninth Circuit in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). Under the *Sequoia Orange* standard, the court will permit government dismissal of FCA claims if it is able to identify a valid governmental purpose and demonstrate a rational relationship between the dismissal and accomplishment of the valid governmental purpose. *Id.* Once the government has satisfied this burden, the

burden then shifts to the relator opposing the dismissal to show that the government's dismissal is "arbitrary, capricious, or illegal." *Id.* If the relator fails to meet this burden, the court will dismiss the FCA claim. *Id.* Applying the *Sequoia Orange* standard, the district court properly denied the Government's motion to dismiss and found the motion arbitrary and capricious.

The Government then appealed the district court's denial of its motion to dismiss. Importantly, the Government chose not to seek certification of this appeal pursuant to 28 U.S.C. § 1292(b) and instead chose to rely on the collateral-order doctrine to obtain the Seventh Circuit's jurisdiction over the lower court's non-final order. The Seventh Circuit asked the parties to file memoranda addressing whether it had jurisdiction over the appeal of this non-final order. Rather than rule on jurisdiction after reviewing the Parties' memoranda, the Seventh Circuit asked the parties to brief the jurisdictional issue once again when they submitted their briefs. In both submissions, the parties addressed the factors necessary for collateral-

appeal jurisdiction over an order denying the Government's motion to dismiss. In its briefing, the Government unequivocally reiterated that it did not move to intervene. The Government further stated that "it is not a party to the underlying *qui tam* proceedings in this case because it declined to intervene."

Despite clear admission that the Government did not, and never intended to, intervene, the Seventh Circuit created jurisdiction where jurisdiction failed to exist by inventing a motion to intervene for the first time in its order. On August 17, 2020, the Seventh Circuit reversed the district court and remanded with orders to dismiss the claims with prejudice to Relator. In doing so, the Seventh Circuit conducted a new analysis by applying a good-cause standard to a set of facts and procedures not found in the record. Then, somehow, the Seventh Circuit further instructed the district court to dismiss the case *without prejudice* to the Government.

REASONS FOR GRANTING THE WRIT

A. The Seventh Circuit Erroneously Created New Federal Jurisdiction.

There is no question that the Government's appeal to the Seventh Circuit was not based on a final order. Stringent application of the final judgment rule avoids encroachment on the "special role" that district judges play as initial arbiters of the many questions of law and fact that occur in the course of a trial. *Firestone Tire & Rubber Co. v. Risjord*, 449 U.S. 368, 374 (1981).

As this Court has explained, "implicit in § 1291 is Congress' judgment that the district judge has primary responsibility to police the prejudgment tactics of litigants, and that the district judge can better exercise that responsibility if the appellate courts do not repeatedly intervene to second-guess prejudgment rulings." *Richardson-Merrell, Inc. v. Koller*, 472 U.S. 424, 436 (1985). Thus, the Government had to rely on the very narrow collateral-order doctrine to argue for jurisdiction. This narrow and small universe of collaterally appealable

orders is well established and includes only explicit statutory and constitutional immunities. *Digital Equip. Corp. v. Desktop Direct, Inc.*, 511 U.S. 863, 875 (1994). When asked by the Seventh Circuit, twice, to address the appellate jurisdiction, both parties thoroughly briefed the elements required to meet the collateral-order doctrine. The case failed to meet any of the elements required for a court to exercise collateral jurisdiction.

The Seventh Circuit, however, failed to address the case before it under the elements of the collateral-order doctrine. Instead, the Seventh Circuit created a new, unfounded narrative to support a new category of jurisdiction based on the Government's motion to intervene – a motion that never existed. The Seventh Circuit even acknowledged that the Government must intervene before it can file a motion to dismiss. As the record clearly shows, the Government chose not to intervene and never intended to intervene. To paraphrase recent words from Chief Justice John Roberts in *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 207 L. Ed. 2d

353 (2020): This dispute before the Court is not whether the Government can or cannot dismiss the FCA case; the dispute is instead primarily about the procedure it followed in doing so. The Seventh Circuit failed to analyze the procedure supported by the record when it expanded jurisdiction based on procedures that never occurred.

In creating this new category of collateral-order jurisdiction, the Seventh Circuit misinterprets and misapplies this Court's opinion *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2009). Importantly, this Court did not expand federal jurisdiction in *Einstein*. The Seventh Circuit claims *Eisenstein* directed it to treat the Government's motion to dismiss as both a motion to intervene and a motion to dismiss. *Eisenstein* does no such thing. In *Eisenstein*, this Court considered the question of whether the Government is a party to a *qui tam* action under the FCA when it has declined to intervene. *See id.* at 930-31. This Court clearly and unanimously answered: No. *Id.*

The Seventh Circuit's decision to expand its jurisdiction by transforming the record into a motion to intervene is particularly concerning in light of the Government's devout and repeated admissions that it had not intervened, and was not intervening, in the underlying case. In its jurisdictional memorandum, the Government stated that "it is not a party to the underlying *qui tam* proceedings in this case because it declined to intervene." The Government reiterated the same position multiple times throughout its opening brief. Likewise, in its reply brief, the Government's jurisdictional arguments focused solely on its right to a collateral appeal when it files a motion to dismiss without intervening in the case.

Although the Seventh Circuit's opinion suggests that it has no interest in creating new categories of collateral appeals, that is exactly what it does. The Government did not file a motion to intervene. The district court did not rule on a motion to intervene. Thus, the Seventh Circuit erroneously exercised jurisdiction over this case when it failed to acknowledge or analyze whether

the collateral-order doctrine applies to a non-final order denying the Government's motion to dismiss when the Government has unequivocally chosen not to intervene.

B. The Seventh Circuit Inappropriately Relied on New Arguments and Claims Unsupported by the Record.

In addition to creating new jurisdiction, the Seventh Circuit improperly created a brand-new analysis so that it could avoid deciding between the competing standards applicable to a 31 U.S.C. § 3730(c)(2)(A) dismissal.

More than a year after informing the district court that it chose not to intervene, the Government filed a motion to dismiss arguing that it should have unfettered and unreviewable dismissal power under 31 U.S.C. § 3730(c)(2)(A). Recognizing a split among federal courts in the applicable standard, the Government also argued that it met the *Sequoia Orange* "rational basis" standard for dismissal. Rather than including any supporting evidence for dismissal in its motion, the Government instead chose to spend almost all of the pages making personal attacks against the Relator. This is the arbitrary and capricious

foundation on which the Government readily and willingly chose to base its motion to dismiss. The district court analyzed briefing and conducted a thorough hearing, after which it correctly adopted the *Sequoia Orange* standard and found that the Government's arbitrary and capricious foundation failed to meet the standard for dismissal.

Like it did with the jurisdictional question, the Seventh Circuit completely, and erroneously, avoided the issue. By transforming the case and ignoring the procedures, the Seventh Circuit applied a new "good cause" analysis to the Government's motion to intervene—a motion that does not exist. Despite the fact that neither the parties nor the district court addressed a good cause analysis for a motion to intervene, the Seventh Circuit refused to remand the case for the district court to conduct such analysis and somehow concluded that the district court would abuse its discretion if it denied the nonexistent motion to intervene.

In conducting a brand-new analysis under its new standard, the Seventh Circuit erroneously focused on

unsupported *post hoc* justifications rather than what the record supported. *See SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943) ("Permitting agencies to invoke belated justifications, on the other hand, can upset "the orderly functioning of the process of review.'"); *see also American Textile Mfrs. Institute, Inc. v. Donovan*, 452 U.S. 490, 539 (1981) ("The functional reasons for requiring contemporaneous explanations apply with equal force regardless whether post hoc justifications are raised in court by those appearing on behalf of the agency or by agency officials themselves."). After Relator and the district court outlined the shortcomings of the motion to dismiss, the Government subsequently started grasping for new, conclusory justifications to dismiss the case. Unsurprisingly, it struggled to support these new conclusions.

For example, the Seventh Circuit states, "The government proposed to terminate this suit in part because, across nine cited agency guidance, advisory opinions, and final rulemakings, it has consistently held

that the conduct complained of is probably lawful. Not only lawful, but beneficial to patients and the public." To the contrary, the Government has never stated that the conduct is "probably lawful," nor does the record support that inference. After the Government was pressed for substance to support its motion, it cited only to the 2016 Revisions to the Safe Harbors Under the Anti-Kickback Statute ("AKS") and the Civil Monetary Penalty Rules Regarding ("CMP") Beneficiary Inducements, published at Fed. Reg. 88368-01 at 88396 (Dec. 7, 2016) ("Final Rule"). Broadly, the AKS deals with giving something of value to prescribers, as alleged in the underlying case, while the CMP deals with giving something of value to beneficiaries/patients, which is not alleged in the underlying case. This Final Rule does not include any safe harbor provision for the allegations and claims brought by Relator. In searching for justification to support its motion to dismiss "after the fact," the Government distorted this case into something was never alleged. Thus, stating that the Government concluded that the alleged conduct is

"probably lawful" under the AKS is manifest error and unsupported by the record.

Worse, in the Final Rule, the Office of the Inspector General ("OIG") specifically rejected a proposal to incorporate a safe harbor provision for the alleged conduct into the AKS. Notwithstanding what OIG explicitly stated in the guidance cited by the Government in its brief, the Seventh Circuit overrides the OIG and the Final Rule and effectively creates a new safe harbor to the AKS conduct alleged. Thus, the Seventh Circuit's holding is unsupported by the evidence in the record as is its justification for creating a new analysis in the first place.

C. The Seventh Circuit's Ruling Violates Procedural Due Process.

Finally, the Seventh Circuit grossly violated Procedural Due Process. Holding that only exceptional cases will warrant a § 3730(c)(2)(A) hearing disregards fundamental procedural due process protections inherent in FCA statute. The Seventh Circuit correctly recognized that the FCA "gives the relator himself an interest in the

lawsuit," and it is well-established that a statutory entitlement is a recognized property interest protected by procedural due process. *See Fuentes v. Shevin*, 407 U.S. 67, 86 (1983); *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428 (1982). Likewise, a right of action is a constitutionally recognized property interest protected by due process. *See Tulsa Prof'l Collection Servs. v. Pope*, 485 U.S. 478, 485 (1988). Accordingly, procedural due process demands that a relator be provided a meaningful hearing before being divested of his or her statutory interest. *See Goldberg v. Kelly*, 397 U.S. 254 (1970); *Leavell v. Illinois Dep't of Nat. Res.*, 600 F.3d 798, 804–05 (7th Cir. 2010).

The Seventh Circuit's acceptance of the Government's policy arguments at face value also raises procedural due process concerns. Procedural due process protections do not implicate the egregiousness of the action itself, but rather consider whether the process accorded was constitutionally sufficient. This Court has long recognized that "where governmental action seriously injures an individual, and the reasonableness of the action

depends on fact findings, the evidence used to prove the Government's case must be disclosed to the individual so that he has an opportunity to show that it is untrue." *Greene v. McElroy*, 360 U.S. 474, 496 (1959). As explained above, the record fails support the Government's justification for seeking to dismiss the claims with prejudice to Relator.

Moreover, the FCA instructs the district court not to limit the status and rights of a relator when permitting the government to intervene. § 3730(c)(3). Relator's rights were undoubtedly limited when the Seventh Circuit sua sponte created a motion to intervene for the Government, permitted the Government to intervene, expanded jurisdiction, conducted its own good-cause analysis, and dismissed all claims with prejudice to Relator but not to the Government, even where the record failed to support dismissal. *See Strasburger v. Bd. of Educ., Hardin County Cmty. Unit Sch. Dist. No. 1*, 143 F.3d 351, 358 (7th Cir. 1998) ("To show a failure of due process, a plaintiff might show that state procedures as written do not supply basic

due process or that state officials acted in a[ ] 'random and unauthorized' fashion in depriving the plaintiff of his protected interest."). *See also Leavell*, 600 F.3d at 804–05. Relators clearly have a statutorily defined interest in a False Claims Act case that they file on behalf of the Government, and allowing the Government dismiss a case with prejudice to the Relator but without prejudice to itself violated procedural due process and, worse, created precedent for future due process violations.

D. This Court's Intervention is Necessary to Resolve a Split Among the Lower Courts.

This Court should resolve the circuit split among competing standards applicable to the government's attempt to dismiss a False Claims Act case under §3730(c)(2)(A). This Court has not yet provided guidance on the standard for dismissal of a *qui tam* action under 3730(c)(2)(A), and the lower courts are growing increasingly inconsistent in the procedure and standard for dismissal. The primary competing standards are outlined in *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir.

2003), which allows the Government to unfettered dismissal not subject to judicial review, and *Sequoia Orange*, 151 F. 3d 1139, which provides for rational-basis based review.

The Ninth and Tenth Circuits have adopted the rational-basis-type test outlined in *Sequoia Orange*. *Sequoia Orange*, 151 F.3d 1139; *Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 936 (10th Cir. 2005). The D.C. Circuit adopted the contrary standard of an unfettered right of dismissal for the Government. *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003).

District courts are also increasing inconsistency by applying competing standards with some applying the *Sequoia Orange* standard, *SMSPF, LLC v. EMD Serono*, Inc., 370 F. Supp. 3d 483 (E.D. Pa. 2019); *United States v. Fiske*, 968 F. Supp. 1347, 1354–55 (E.D. Ark. 1997); *Nasuti ex rel. U.S. v. Savage Farms, Inc.*, No. CIV.A. 12-30121-GAO, 2014 WL 1327015, at *10 (D. Mass. Mar. 27, 2014), aff'd sub nom. *Nasuti v. Savage Farms Inc.*, No. 14-1362, 2015 WL 9598315 (1st Cir. Mar. 12, 2015), and others

supporting an unfettered right of dismissal, *United States ex rel. Farmer v. Republic of Honduras*, 438 F. Supp. 3d 1321, 1330 (S.D. Ala. 2020); *United States ex rel. Vanderlan v. Jackson HMA, LLC*, No. 3:15-CV-767-DPJ-FKB, 2021 WL 41310, at *3 (S.D. Miss. Jan. 5, 2021).

The Second Circuit Court of Appeals recently acknowledged the split but declined to decide which standard should govern. *United States ex rel. Borzilleri v. AbbVie, Inc.*, No. 19-2947-CV, 2020 WL 7039048, at *2 (2d Cir. Dec. 1, 2020). Similarly, the Third Circuit noted the circuit split on the standard applicable to Section 3730(c)(2)(A) in two recent opinions but expressly declined to take a position. *See Bookwalter v. UPMC*, 938 F.3d 397, 417 (3d Cir. 2019) ("[O]ur Court has not yet specified the standard of review for a [Section] 3730(c)(2)(A) dismissal"); *Chang v. Children's Advocacy Ctr. of Del.*, 938 F.3d 384, 387 (3d Cir. 2019) ("We need not take a side in the [Ninth/Tenth v. District of Columbia] circuit split because [relator] fails even the more restrictive standard.").

Now, the Seventh Circuit has seemingly created a different standard to apply to a motion to dismiss under 31 U.S.C. § 3730(c)(2)(A) by treating it as a motion to intervene and applying a good cause standard, further increasing the inconsistency and split among the federal courts. This Court should grant this Petition in order to resolve the growing inconsistency among the lower courts and establish the appropriate standard for § 3730(c)(2)(A) dismissal.

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APPENDIX A

In the

United States Court of Appeals

For the Seventh Circuit

No. 19-2273

UNITED STATES OF AMERICA ex rel. CIMZNHCA, LLC,
Plaintiff-Appellee,

v.

UCB, INC., et al.,
Defendants,

Appeal of:
UNITED STATES OF AMERICA,
Appellant.

Appeal from the United States District Court for the
Southern District of Illinois.
No. 3:17-cv-00765-SMY-MAB — **Staci M. Yandle**, *Judge*.

ARGUED JANUARY 23, 2020 — DECIDED AUGUST 17, 2020

Before ROVNER, HAMILTON, and SCUDDER, *Circuit Judges*.

HAMILTON, *Circuit Judge*. The False Claims Act allows the United States government to dismiss a relator's qui tam suit over the relator's objection with notice and opportunity for a hearing. 31 U.S.C. § 3730(c)(2)(A). The Act does not indicate

how, if at all, the district court is to review the government's decision to dismiss. The D.C. Circuit has said not at all; the Ninth Circuit has said for a rational basis. Compare *Swift v. United States*, 318 F.3d 250 (D.C. Cir. 2003), with *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). In this case, the district court said it agreed with the Ninth Circuit but applied something closer to administrative law's "arbitrary and capricious" standard and denied dismissal. The government has appealed. The relator contends we should either dismiss for want of appellate jurisdiction or affirm.

We find that we have jurisdiction and reverse. First, we interpret the Act to require the government to intervene as a party before exercising its right to dismiss under § 3730(c)(2)(A). We think it best, however, to construe the government motion here as a motion to both intervene and dismiss. This solves the jurisdictional problem without needing to create a new category of collateral-order appeals. On the merits, we view the choice between the competing standards as a false one, based on a misunderstanding of the government's rights and obligations under the False Claims Act. And by treating the government as seeking to intervene, which it should have been allowed to do, we can apply a standard for dismissal informed by Federal Rule of Civil Procedure 41.

I. Factual and Procedural Background

In 1863, "a series of sensational congressional investigations" revealed that war-profiteering military contractors had billed the federal government for "nonexistent or worthless goods, charged exorbitant prices for goods delivered, and generally robbed" the government's procurement efforts. *United States v. McNinch*, 356 U.S. 595, 599 (1958). In response,

Congress passed the False Claims Act, now codified at 31 U.S.C. §§ 3729–3733. The Act authorizes a private person, called a relator, to enforce its terms by filing suit "for the person and for the United States Government." § 3730(b)(1). Suits of this type were once so common that "[a]lmost every" penal statute could be enforced by them. *Adams v. Woods*, 6 U.S. (2 Cranch) 336, 341 (1805). Such suits are called "qui tam" suits, from a Latin tag meaning, "who as well for the lord king as for himself sues in this matter." If the relator's qui tam action is successful, she receives a portion of the recovery as a bounty; the lion's share goes to the government. § 3730(d).

The False Claims Act prohibits, among other acts, presenting to the government "a false or fraudulent claim for payment or approval." § 3729(a)(1)(A). One way to present a false claim is to present to a federal healthcare program a claim for payment that violates the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), which prohibits giving or receiving "remuneration" in return for such programs' business. See 42 U.S.C. § 1320a-7b(g) (violations of the Anti-Kickback Statute also violate the False Claims Act). For a limited liability company called Venari Partners, doing business as the "National Health Care Analysis Group," this law presented a business opportunity.

Venari Partners has four members (Sweetbriar Capital, LLC; 101 Partners, LLC; Min-Fam-Holding, LLC; and Uptown Investors, LP), themselves composed of one or two individual investors, six in total. Venari Partners formed eleven daughter companies, each for the single purpose of prosecuting a separate qui tam action. All eleven actions allege essentially identical violations of the False Claims Act via the Anti-

Kickback Statute by dozens of defendants in the pharmaceutical and related industries across the country.

The relator in this case is CIMZNHCA, LLC, one of those Venari companies. Its complaint, filed in 2017 in the Southern District of Illinois, alleges that defendants illegally paid physicians for prescribing or recommending Cimzia, a drug manufactured by defendant UCB, Inc. to treat Crohn's disease, to patients who received benefits under federal healthcare programs. The relator alleges that the illegal kickbacks took the form of free education services provided by nurses to physicians and their patients and free reimbursement support services, that is, assistance with insurance paperwork.

Once the relator filed this action, the government had the right "to intervene and proceed" as the plaintiff with the "primary responsibility" for prosecuting it. 31 U.S.C. §§ 3730(b)(2), 3730(c)(1). The government chose not to exercise that right. The False Claims Act also gives the government the right to dismiss the action over the relator's objection if the relator is provided notice and an opportunity for a hearing. § 3730(c)(2)(A). This right the government has sought to exercise. On December 17, 2018, the government filed a motion to dismiss, representing that it had investigated the Venari companies' claims, including CIMZNHCA's, and found them "to lack sufficient merit to justify the cost of investigation and prosecution and otherwise to be contrary to the public interest." The district court held a hearing on the government's motion and issued an opinion denying it.

The court considered first what standard of review applied to the government's motion under § 3730(c)(2)(A), which itself supplies none. The government urged adoption of the standard announced in *Swift v. United States*, 318 F.3d

250, 253 (D.C. Cir. 2003), which gives the government "unfettered" discretion to dismiss. Relator argued for the more demanding burden-shifting test announced in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). Under that test, the government must first identify a "valid government purpose" and then show "a rational relation between dismissal and accomplishment of the purpose." *Id.* at 1145. If the government does so, the burden shifts to the relator to show that "dismissal is fraudulent, arbitrary and capricious, or illegal." *Id.*

Reasoning that Congress would not command the hollow ritual of convening a hearing on a preordained outcome (no one deliberates about the fall of Troy, as Aristotle said), the district court concluded that *Sequoia Orange* supplied the proper standard. Deeming the government's general evaluation of the Venari companies' claims to be insufficient as to CIMZNHCA in particular, and hearing notes of mere "animus towards the relator" in the government's arguments, the court concluded further that the government's decision to dismiss was "arbitrary and capricious" and "not rationally related to a valid governmental purpose."

After the district court denied its motion to reconsider, the government took this appeal, pending which the district court proceedings have been stayed. Our jurisdiction is contested. On the merits, the government argues that *Swift*, not *Sequoia Orange*, supplies the proper standard and that it satisfied the Ninth Circuit's test in any event. Relator argues that *Swift* should be rejected and that the district court correctly applied *Sequoia Orange*. We conclude first that we have jurisdiction and second that the choice presented to us on the merits is a false one, though the correct answer lies much nearer to *Swift*

than *Sequoia Orange*. We reverse and remand with instructions to dismiss this action.

II. Analysis

A. The False Claims Act

We begin with an overview of the False Claims Act's most relevant provisions.[1] A qui tam action under the Act is brought "for the person and for the United States Government" and must be filed "in the name of the Government." 31 U.S.C. § 3730(b)(1). The relator may voluntarily dismiss the action "only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting." *Id.*

The relator's complaint must be filed under seal and may not be served on the defendants until the court so orders. § 3730(b)(2). Upon filing, the relator must serve the government with a copy of the complaint and a "written disclosure of substantially all material evidence" in the relator's possession. *Id.* The government then has sixty days, *id.*, extendable for "good cause shown," § 3730(b)(3), to decide whether "to intervene and proceed with the action" while the complaint remains under seal. § 3730(b)(2). At the end of the seal period, "the Government shall (A) proceed with the action, in which case the action shall be conducted by the Government; or (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action." § 3730(b)(4).

Before 1986, if the government intervened in the action, the relator's participation was at an end. In 1986, however,

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[1] The text of 31 U.S.C. § 3730(b)–(c) is attached as an appendix to this opinion.

Congress amended the False Claims Act to allow for the relator's continued participation even after the government intervenes. Allowing two plaintiffs has given rise to a new set of tensions that the provisions at the heart of this case were designed to manage. See *Sequoia Orange*, 151 F.3d at 1143–44, citing *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 745 (9th Cir. 1993), among others. "If the Government proceeds with the action," it assumes "primary responsibility" for prosecuting it. § 3730(c)(1). The relator retains "the right to continue as a party to the action," but critically for our purposes, that right is "subject to the limitations set forth in paragraph (2)." *Id.*

The most relevant of these limits is the government's right to dismiss the action:

> The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

§ 3730(c)(2)(A). The other limits are the government's right to settle the action "notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances," § 3730(c)(2)(B); the government's right to seek a court order restraining the relator's abusive litigation conduct, § 3730(c)(2)(C); and the defendant's right to do the same. § 3730(c)(2)(D).

"If the Government elects not to proceed with the action," the relator "shall have the right to conduct the action." § 3730(c)(3). The relator's sole obligations to the government

thereafter are to supply it on request with copies of all pleadings and, at the government's expense, copies of all deposition transcripts. *Id.* The court may "nevertheless permit the Government to intervene at a later date upon a showing of good cause." *Id.* "Whether or not the Government proceeds with the action," the government may seek a stay of discovery if it would interfere with an ongoing investigation into the same facts. § 3730(c)(4). Finally, if the government elects to pursue "any alternate remedy" for the challenged conduct, the relator may not be cut out; she has "the same rights" in the alternate proceeding as in the qui tam action. § 3730(c)(5).

B. Appellate Jurisdiction: Appeal from the Denial of a Motion to Intervene

We must decide our jurisdiction first. *West v. Louisville Gas & Elec. Co.*, 920 F.3d 499, 503 (7th Cir. 2019). Ordinarily we have appellate jurisdiction of the district courts' final judgments under 28 U.S.C. § 1291 and a few categories of interlocutory orders under § 1292. Denials of motions to dismiss rarely fit into those categories, but the government argues here that the denial of its motion to dismiss under 31 U.S.C. § 3730(c)(2)(A) was a "collateral order," not a final judgment but by a "practical construction" of 28 U.S.C. § 1291 still a "final decision" within its terms. See *Ott v. City of Milwaukee*, 682 F.3d 552, 554 (7th Cir. 2012) (internal quotation marks omitted). We see no need to create a new category of appealable collateral orders. In substance, the government appeals a denial of what should be deemed a motion to intervene and then to dismiss. It is well established that denials of motions to intervene are appealable.

Collateral orders are orders that are final with respect to the issue they decide and important enough to be immediately appealable. *Mohawk Industries v. Carpenter*, 558 U.S. 100, 103 (2009), citing *Cohen v. Beneficial Indus. Loan Corp.*, 337 U.S. 541, 546 (1949). Protecting the default rule of one appeal per case, however, means that the universe of appealable collateral orders "must remain narrow and selective in its membership." *Mohawk Industries*, 558 U.S. at 113, quoted in *Ott*, 682 F.3d at 555. The question is not whether the particular order is collateral but whether "the entire category" of orders to which it belongs is. *JPMorgan Chase Bank, N.A. v. Asia Pulp & Paper Co.*, 707 F.3d 853, 868 (7th Cir. 2013), quoting *Mohawk*, 558 U.S. at 107.

This categorical analysis is difficult here because the type of order appealed here is very rare. In the history of the False Claims Act since 1986, the government tells us, only one other district court has denied its § 3730(c)(2)(A) motion to dismiss, which the Ninth Circuit recently declined to hold a collateral order.[2] The power of a non-party to force dismissal of another's lawsuit is otherwise unheard of in our law. See, e.g., Fed. R. Civ. P. 17(a)(3) (real party in interest must "ratify, join,

[2] *United States v. Academy Mortgage Corp.*, No. 3:16-cv-02120-EMC, 2018 WL 3208157, at *2–*3 (N.D. Cal. June 29, 2018), appeal dismissed sub nom. *United States ex rel. Thrower v. Academy Mortgage Corp.*, No. 18-16408, F.3d , 2020 WL 4462130 (9th Cir. Aug. 4, 2020). The Ninth Circuit in *Thrower* rejected the government's argument that an order denying a motion to dismiss under 31 U.S.C. § 3730(c)(2)(A) is appealable as a collateral order. The *Thrower* court was not presented with and did not consider the possibility of treating the government's motion to dismiss as a motion both to intervene and to dismiss, as suggested in *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003), which is the path we follow in finding that we have jurisdiction over this appeal, as explained below.

or be substituted into" action brought on its behalf); *Minneapolis-Honeywell Regulator Co. v. Thermoco, Inc.*, 116 F.2d 845,847 (2d Cir. 1941) (L. Hand, J.) ("[T]he companies could not make any motion unless they became parties … although they might … have combined a motion to intervene with a motion to dismiss.").

1. Eisenstein, Footnote 2

The government argues that the jurisdictional issue has already been resolved in its favor by *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2009), the Supreme Court's most recent word on the relationship between the relator and the government in a qui tam case in which the government has declined to intervene. The holding of *Eisenstein* is that, absent intervention, the government is not a "party" for the purpose of determining applicable appeal deadlines. 556 U.S. at 937; see 28 U.S.C. § 2107(b) (deadline where United States is "party"); Fed. R. App. P. 4(a)(1)(B) (same). Along the way, the Court observed that, the government's non-party status notwithstanding, it need not intervene to appeal "any order" in a qui tam suit. 556 U.S. at 931 n.2. Rather, its immediate appeal would lie from the relator's voluntary dismissal of the case without the government's written consent. *Id.*, citing 31 U.S.C. § 3730(b)(1). And denials of motions to intervene have long been held immediately appealable. *Id.*, citing § 3730(c)(3).

The government maintains there is "no basis for distinguishing" *Eisenstein*'s examples from an order *denying* a motion to a dismiss under § 3730(c)(2)(A). But the bases are obvious: voluntary dismissal ends the case, and the immediate appealability of a denial of intervention is even older than the collateral-order doctrine announced in *Cohen*. See *Brotherhood*

of R.R. Trainmen v. Baltimore & Ohio R.R. Co., 331 U.S. 519, 524–25 (1947). Footnote 2 of *Eisenstein* does not stand for the proposition stated by the government. It nonetheless indicates the correct path to solving the jurisdictional problem: treat the government's motion to dismiss as a motion both to intervene and to dismiss.

2. Intervention in Substance

An intervenor comes between the original parties to ongoing litigation and interposes between them its claim, interest, or right, which may be adverse to either or both of them. See *Eisenstein*, 556 U.S. at 933; *Rocca v. Thompson*, 223 U.S. 317, 330–31 (1912). That is exactly what the government wants to do here. The government claims a superior right to dispose of this lawsuit between the relator and the defendants by ending it on terms it deems suitable. The relator holds the present statutory right "to conduct the action," 31 U.S.C. § 3730(b)(4)(B), as well as a partial congressional assignment of any resulting damages, *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773 (2000), both of which the government asserts the right to nullify. The defendants, as their pending motions to dismiss reveal, desire the finality of a dismissal with prejudice. The government asserts the right to deny defendants that finality by having the action dismissed with prejudice as to the relator but without prejudice as to it. In sum, the government wants a say—the final say—in conducting this lawsuit. The district court's order denying that wish is in substance an order denying a motion to intervene.

3. Intervention in Form

There is another reason to construe for jurisdictional purposes the government's motion to dismiss as a motion to intervene and dismiss: it ought to have been filed that way to begin with. Cf. *Swift v. United States*, 318 F.3d 250, 252 (D.C. Cir. 2003) (if government were required to intervene before dismissing, "we could construe the government's motion to dismiss as including a motion to intervene").

As a matter of form, the government did not move to intervene before filing its motion to dismiss under § 3730(c)(2)(A). Several courts of appeals have expressly or tacitly endorsed its prerogative not to do so. *Chang v. Children's Advocacy Ctr. of Del.*, 938 F.3d 384, 386 (3d Cir. 2019); *Ridenour v. Kaiser-Hill Co.*, 397 F.3d 925, 933–34 (10th Cir. 2005); *Swift*, 318 F.3d at 251–52; *United States ex rel. Kelly v. Boeing Co.*, 9 F.3d 743, 753 n.10 (9th Cir. 1993); see also *United States v. Everglades Coll., Inc.*, 855 F.3d 1279, 1285–86 (11th Cir. 2017) (settlements under § 3730(c)(2)(B)). These decisions did not address appeals of denials of dismissal, but adhering to them in this case of a denial would require in effect creation of a new category of appealable collateral orders. The Supreme Court has firmly discouraged that step. See *Mohawk*, 558 U.S. at 113–14.

There is a better solution. We read the False Claims Act as requiring the government to intervene before exercising any right under § 3730(c)(2). Accord, *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 519 (6th Cir. 2009) ("Section 3730(c)(2)(A) applies only when the government has decided to 'proceed[] with the action' and has assumed 'primary responsibility for prosecuting the action.'").

a. Text and Structure of § 3730(c)

To explain our solution of the jurisdictional problem, we begin with the statute's text. E.g., *Ross v. Blake*, 136 S. Ct. 1850, 1856 (2016). Subsection (c) of § 3730 bears the heading, "Rights of the parties to qui tam actions." One would thus expect subsection (c) to treat the rights of *parties* to qui tam actions, which the government is not unless and until "it intervenes in accordance with the procedures established by federal law." *Eisenstein*, 556 U.S. at 933. In fact, the structure of subsection (c) guides its proper interpretation as to which rights litigants possess under which procedural circumstances. See *Ortega v. Holder*, 592 F.3d 738, 743 (7th Cir. 2010) ("we must consider not only the words of the statute, but also the statute's structure."). Each paragraph of subsection (c)—except paragraph (2)—announces at its outset the procedural posture to which it applies. Paragraph (1) applies "If the Government proceeds with the action." Paragraph (3) applies "If the Government elects not to proceed with the action." Paragraph (4) applies "Whether or not the Government proceeds with the action." Paragraph (5) applies "Notwithstanding subsection (b)," that is, notwithstanding the relator's qui tam action altogether. Where, then, does paragraph (2) fit into this structure?

Nowhere, the D.C. Circuit answered in *Swift*. According to *Swift*, paragraph (2) is entirely free-floating; it is not "constrained by" and operates "independent[ly] of" the rest of subsection (c), including specifically paragraph (1). 318 F.3d at 252. There are several reasons to question this reading. First, it makes surplusage of paragraph (4)'s introductory phrase, "Whether or not the Government proceeds with the action." But see, e.g., *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339

(1979) (anti-surplusage canon); see also Antonin Scalia & Bryan A. Garner, *Reading Law* 156 (2012) ("Material within an indented subpart relates only to that subpart."). If the background assumption of subsection (c) were that each of its paragraphs applied no matter whether the government had intervened, Congress would not have specified that paragraph (4), and only paragraph (4), applies "Whether or not the Government proceeds with the action."

The *Swift* analysis also makes surplusage of the provision in paragraph (1) that a post-intervention relator has the right to continue as a party "subject to the limitations set forth in paragraph (2)." Again, if the government enjoyed its rights under paragraph (2) under all circumstances and in any posture, there would have been no reason to specify that the relator's continued participation as a party, and only the relator's continued participation as a party, is "subject to" paragraph (2).

Along these lines, § 3730(b)(4)(B) gives the relator "the right to conduct the action"—without qualification—when the government has declined to intervene. That phrase is picked up by paragraph (c)(3), which provides that, "If the Government elects not to proceed with the action," the relator "shall have the right to conduct the action," while reserving certain rights (to be served with copies of certain papers, to intervene later for good cause) to the government. Thus, when Congress wanted to qualify the relator's "right to conduct the action" absent intervention, it did so in paragraph (c)(3). It would be odd if the unqualified "right to conduct the action" in subparagraph (b)(4)(B) and the nearly unqualified "right to conduct the action" in paragraph (c)(3) were in fact the profoundly qualified right to conduct the action so long as the

government does not wish to have it dismissed or settled under subparagraphs (c)(2)(A) or (B)—neither of which even mentions the relator's "right to conduct the action."

So where does paragraph (2) best fit in? The second half of the paragraph plainly operates against the backdrop of government intervention. Specifically, subparagraph (C) provides for "limitations" on the relator's participation where its "unrestricted participation … would interfere with or unduly delay *the Government's prosecution* of the case." (Emphasis added.) Similarly, subparagraph (D) provides that the relator's "participation" may be "limit[ed]" where its "unrestricted participation" would harass or unduly burden the defendant. Obviously a defendant cannot "restrict the participation" of its sole adversary in a lawsuit. We find subparagraph (D) even more telling than subparagraph (C) for our purposes because subparagraph (C) makes the government's participation explicit while subparagraph (D) tacitly assumes it—suggesting that so too does the rest of paragraph (2).

We conclude that paragraph (2) fits in best right where paragraph (1) puts it: as a limit on the right of the relator to continue as a party after the government has intervened. It can have no other independent operation without disrupting the structure of the statute as a whole. *Swift* reasoned that, to justify this reading, "either § 3730(c)(2) would have to be a subsection of § 3730(c)(1)—which it is not—or § 3730(c)(2) would have to contain language stating that it is applicable only in the context of § 3730(c)(1)—which it does not." 318 F.3d at 252. The first minor premise, that paragraph (c)(2) is not a subsection of paragraph (c)(1), is true as a typographic matter but otherwise fails to capture how the five paragraphs of subsection (c) relate to one another in text and logic. As our

premises differ, so too does our conclusion: paragraph (c)(2) is better read to operate only "If the Government proceeds with the action." § 3730(c)(1).

The remaining arguments advanced by *Swift* and cases adopting its reading against a need for intervention to dismiss are not persuasive. First, *Swift* neutered the binary choice put to the government by Congress—intervene, § 3730(b)(4)(A), or decline, § 3730(b)(4)(B)—by finding a third way to dismiss without intervention under § 3730(c)(2)(A). From the provision that the government "may elect to intervene *and proceed* with the action," § 3730(b)(2), the court reasoned that "[e]nding the case by dismissing it is not proceeding with the action; to 'proceed with the action' means … that the case will go forward with the government running the litigation." 318 F.3d at 251. Accord, *Everglades Coll., Inc.*, 855 F.3d at 1285 (settlement under § 3730(c)(2)(B)); *Ridenour*, 397 F.3d at 933.

In our view, this awkward reading of the provision is not the better reading. "Proceeding" in the litigation context is chiefly defined as "the regular and orderly progression of a lawsuit." *Proceeding*, Black's Law Dictionary (4th ed. 2011). We find no support in *Swift* or elsewhere for the proposition that the regular and orderly progression of a lawsuit requires litigating to favorable judgment or involuntary dismissal, to the exclusion of voluntary dismissal, particularly upon settlement. If "proceed" were understood that way, how much litigating would the government have to do before it could then dismiss without running afoul of the command to "proceed"? This reading of "proceed" suggests further that "electing not to proceed" would include electing to dismiss voluntarily. That cannot be right because paragraph (c)(3) gives the relator "the right to conduct the action" where "the Government

elects not to proceed with the action." One cannot "conduct" a lawsuit that has been dismissed.

b. Serious Constitutional Doubts?

Second, the Tenth Circuit in *Ridenour*, invoking the Take Care Clause of Article II, § 3, and the constitutional-doubt canon of statutory interpretation, see *Zadvydas v. Davis*, 533 U.S. 678, 689 (2001), rejected the reading we adopt here in part because "to condition the Government's right … to dismiss an action in which it did not initially intervene upon a requirement of … good cause [under § 3730(c)(3)] would place the FCA on constitutionally unsteady ground" by "unnecessarily bind[ing] the Government." 397 F.3d at 934; see also *Kelly*, 9 F.3d at 753 n.10 (because statute does not "prohibit[]" it, interpretation allowing dismissal without intervention is "entirely appropriate" as illustration of "meaningful [executive] control" over relators' FCA suits). Respectfully, we do not find constitutional doubt a sound reason to follow this path.

The canon of constitutional doubt teaches that when two interpretations of a statute are "fairly possible," one of which raises a "serious doubt" as to the statute's constitutionality and the other does not, a court should choose the interpretation "by which the question may be avoided." *Zadvydas*, 533 U.S. at 689; see *United States ex rel. Att'y General v. Del. & Hudson Co.*, 213 U.S. 366, 407–08 (1909). The canon does *not* hold that any reading of a statute not expressly "prohibited" must be adopted if it will relieve the executive of any burden of undefined weight which the judiciary deems without analysis to be "unnecessary." But that is how the canon was applied in *Ridenour* and *Kelly*. In our view, this analysis is misguided for two reasons. First, it indulges every presumption in favor of

the statute's invalidity rather than its validity. Second, it simply does not show that the False Claims Act is in serious danger of unconstitutionality unless dismissal under § 3730(c)(2)(A) applies only after the government has declined to intervene.

First, *Ridenour* and *Kelly* inverted the constitutional-doubt canon, and constitutional avoidance principles generally, by creating constitutional problems in one section of a statute to solve them in a different section of the statute. "Good cause" is a uniquely flexible and capacious concept. See *Good Cause*, s.v. *Cause*, Black's Law Dictionary (4th ed. 2011) ("A legally sufficient reason."). But neither *Ridenour* nor *Kelly* offered an interpretation of what constitutes "good cause" under § 3730(c)(3). Neither acknowledged the variety of situations calling for that decision.[3] Both assumed without analysis that any "good cause" requirement would tend to fetter the executive unconstitutionally—neglecting, at minimum, the possibility that avoiding offense to the separation of powers in a case that actually risks it would itself weigh heavily in any "good cause" determination.

[3] For example, the Article II implications of denying good cause to intervene could vary widely. Compare a case where the government seeks to dismiss at an early stage because it has consistently held the challenged conduct to be lawful and desirable, to a case where the government seeks to dismiss on the eve of trial of meritorious claims only to protect a high-ranking executive official's private business interests. See *Yick Wo v. Hopkins*, 118 U.S. 356, 372–74 (1886), cited by *Heckler v. Chaney*, 470 U.S. 821, 838 (1985); see also Andrew Kent et al., *Faithful Execution and Article II*, 132 Harv. L. Rev. 2111 (2019) (original public meaning of duty to "faithfully execute" was "fiduciary").

Both decisions thus defaulted to the most constitutionally offensive reading of § 3730(c)(3) rather than the least. Both thereby created rather than avoided doubtful questions of constitutional law, which then required "solving" by doubtful interpretation of § 3730(c)(2)(A). Our duty, though, is to indulge "[e]very presumption … in favor of the validity of the statute." *Graves v. Minnesota*, 272 U.S. 425, 428 (1926). Our reading of § 3730(c)(2)(A), by contrast, presumes § 3730(c)(3) is valid on its face and simply defers consideration of genuine constitutional concerns until they ripen in a specific context and are thus more properly presented for decision. See *Ashwander v. T.V.A.*, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring).

Second, because neither *Ridenour* nor *Kelly* offered an account of what "good cause" requires nor of what Article II requires in relation to "good cause" dismissals, neither decision raises a serious possibility that the constitutionality under Article II of the False Claims Act depends on a particular construction of § 3730(c)(2)(A). As a general matter, the Supreme Court has reserved decision on the constitutionality under Article II of qui tam actions. *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 778 n.8 (2000). Their ancient pedigree, however, together with their widespread use at the time of the Founding, suggests that the False Claims Act as a whole is not in imminent danger of unconstitutionally usurping the executive power. See *id.* at 774–77 ("originated around the end of the 13th century"); *Marvin v. Trout*, 199 U.S. 212, 225 (1905) ("in existence for hundreds of years in England, and in this country ever since the foundation of our government"); *Adams v. Woods*, 6 U.S. (2 Cranch) 336, 341 (1805) (Marshall, C.J.) ("Almost every fine or forfeiture under a penal statute, may be recovered by an action of debt [qui tam]."); 3

William Blackstone, Commentaries *160 (Forfeitures created by penal statutes "more usually are given at large, to any common informer; or … to the people in general … . [I]f any one hath begun a *qui tam*, or *popular*, action, no other person can pursue it; and the verdict passed upon the defendant … is … conclusive even to the king himself."). Indeed, a common function of qui tam actions, and one of the earliest, has been to regulate the exercise of executive power itself. Randy Beck, *Qui Tam Litigation Against Government Officials*, 93 Notre Dame L. Rev. 1235, 1260–61 (2018) (discussing Statute of York 1318, 12 Edw. 2); *id.* at 1269–1304 (early American use of such qui tam actions).

While reserving decision on the Article II consequences, as a matter of statutory interpretation, *Stevens* rejected an agency theory of the government-relator relationship under the False Claims Act: "to say that the relator here is simply the statutorily designated agent of the United States, in whose name … the suit is brought … is precluded … by the fact that the statute gives the relator himself an interest *in the lawsuit*." 529 U.S. at 772 (some emphasis omitted). That interest is reflected in the rights retained by the relator even after the government has intervened. *Id.*, citing § 3730(c)(1), (c)(2)(A), & (c)(2)(B). It is reflected as well in "the right to conduct the action" that indisputably belongs to the relator once the government declines to intervene and can be wrested from the relator later only on a showing of good cause. § 3730(b)(4)(B) & (c)(3). That right includes, for example, the right to choose which claims to pursue, the right to engage the machinery of discovery, and the right to settle claims without government oversight (excepting the government's veto power under § 3730(b)(1) if the settlement is entered as a voluntary dismissal, though it need not be).

We are not persuaded that a serious marginal risk of unconstitutionality is created by including dismissal in the list of powers reclaimable by the government only for good cause. The power to terminate the action is simply part of the power "to conduct the action." See Fed. R. Civ. P. 41(a); see also *Kelly*, 9 F.3d at 754 & n.14 ("[O]nce prosecution has been initiated, the government has greater authority to … ultimately *end* the litigation in a qui tam action than it does in an independent counsel's action;" true no matter whether § 3730(c)(2)(A) requires intervention), applying *Morrison v. Olson*, 487 U.S. 654 (1988). The government's automatic intervention rights during the seal period are themselves extendable only for "good cause," § 3730(b)(3), and even in criminal cases, the government must have "leave of court" to dismiss the prosecution. Fed. R. Crim. P. 48(a); *Rinaldi v. United States*, 434 U.S. 22, 29–32 (1977). Accordingly, we do not see a serious possibility that the constitutionality of the False Claims Act will stand or fall on a requirement that the government show good cause to intervene and dismiss after its automatic intervention rights have expired.

We have warned before that the constitutional-doubt canon "must be used with care, for it is a closer cousin to invalidation than to interpretation. It is a way to enforce the constitutional penumbra." *United States v. Marshall*, 908 F.2d 1312, 1318 (7th Cir. 1990) (en banc); see also Richard A. Posner, *The Federal Courts* 285 (1985) (The canon "enlarge[s] the … reach of constitutional prohibition … to create a … 'penumbra' that has much the same prohibitory effect as the … Constitution itself.").

The application of the canon in *Ridenour* and *Kelly* illustrates this warning. The canon can produce a hazy penumbra

of quasi-constitutional law that is used to limit legislative power when statutes are construed, without constitutional adjudication of a concrete case or controversy, to exclude all "unnecessar[y]" executive restrictions and to require all "entirely appropriate" executive prerogatives. See *Ridenour*, 397 F.3d at 934; *Kelly*, 9 F.3d at 753 n.10.

Our task is not to chip away at the legislation under the guise of interpreting it until every conceivable constitutional concern is assuaged. See *Salinas v. United States*, 522 U.S. 52, 59–60 (1997), citing among others *United States v. Albertini*, 472 U.S. 675, 680 (1985). Our task is to apply the Act until a party with standing convinces us or the Supreme Court that to do so would be unconstitutional. The constitutional-doubt canon can be used to resolve genuine doubts when the language is ambiguous and the constitutional danger clear and present. *Marshall*, 908 F.2d at 1318. It should not be used where, as here, the constitutional questions are more dubious than the statutory text. Statutory clarity should not yield to penumbral obscurity.

In sum, we treat the government's motion to dismiss as a motion both to intervene and then to dismiss under § 3730(c)(3) because intervention was in substance what the government sought and in form what the False Claims Act requires. Cf. *Swift*, 318 F.3d at 252 ("[I]f there were such a requirement, we could construe the government's motion to dismiss as including a motion to intervene."). The Supreme Court in *Eisenstein* could not "disregard" the "congressional assignment of discretion" to the government to intervene under the Act by treating the government as a party "even after it has declined to assume the rights and burdens attendant to full party status." 556 U.S. at 933–34. Neither will we. The

government cannot eat its cake and have it too. If the government wishes to control the action as a party, it must intervene as a party, as provided for by Congress.

Having concluded that the government's case for dismissal was not even rational, the district court here has necessarily expressed its view on the government's lack of "good cause" to intervene under the Act. Accordingly, we have jurisdiction over the appeal of what amounted to an order denying a motion to intervene. E.g., *Planned Parenthood of Wis., Inc. v. Kaul*, 942 F.3d 793, 796–97 (7th Cir. 2019). We may proceed to the merits.

C. *Merits: The Government Was Entitled to Dismissal*

Treating the government as having sought to intervene solves the jurisdictional problem and offers a standard on the merits of dismissal, in the absence of a specific standard in 31 U.S.C. § 3730(c)(2)(A). The standard is that provided by the Federal Rules of Civil Procedure, as limited by any more specific provision of the False Claims Act and any applicable background constraints on executive conduct in general. In this case, no such substantive limits apply, so the Rules are the beginning and the end of our analysis.

Federal Rule of Civil Procedure 41(a)(1)(A)(i) provides that "the plaintiff may dismiss an action" by serving a notice of dismissal any time "before the opposing party serves either an answer or a motion for summary judgment." Dismissal is without prejudice unless the notice states otherwise. Fed. R. Civ. P. 41(a)(1)(B). This right is "absolute." *Marques v. Federal Reserve Bank of Chi.*, 286 F.3d 1014, 1017 (7th Cir. 2002). "[O]ne doesn't need a good reason, or even a sane or any reason" to

serve notice under the Rule, *id.*, and the notice is self-executing and case-terminating. *Id.* at 1018; *Smith v. Potter*, 513 F.3d 781, 782–83 (7th Cir. 2008). In other words, once a valid Rule 41(a) notice has been served, "the case [is] gone; no action remain[s] for the district judge to take," and her further orders are void. *Smith*, 513 F.3d at 782–83. Here, the government filed its "motion to dismiss" before the defendants had answered or moved for summary judgment, seeking dismissal without prejudice as to it and with prejudice as to the relator. It does not matter that the paper was labeled a "motion" rather than a "notice." *Id.* at 782. That looks like the end of the case, on terms of the government's choosing.

Actually, that was *almost* the end of the case because the provisions of Rule 41(a) are "[s]ubject to … any applicable federal statute." Fed. R. Civ. P. 41(a)(1)(A). By itself, Rule 41(a) provides that "the plaintiff may dismiss an action," *id.*, which obviously does not authorize an intervenor-plaintiff to effect involuntary dismissal of the original plaintiff's claims. See *Washington Elec. Coop., Inc. v. Mass. Mun. Wholesale Elec. Co.*, 922 F.2d 92, 97 (2d Cir. 1990). But § 3730(c)(2)(A) provides otherwise. Picking up the language of Rule 41, the statute provides: "The Government may dismiss the action" without the relator's consent if the relator receives notice and opportunity to be heard. § 3730(c)(2)(A). This procedural limit is the only authorized statutory deviation from Rule 41. Cf. § 3730(c)(2)(B) (authorizing settlement without relator's consent only "if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances"). Nor, because § 3730(c)(2)(A) twice refers to the government's "motion," should the statute be construed to eliminate the right to dismiss under the first half of Rule 41(a), whose language it mirrors. See *Adams v. Woods*, 6

U.S. (2 Cranch) 336, 337, 341 (1805) (Marshall, C.J.) (where statute of limitations provided that no person shall be "*prosecuted, tried or punished* … for *any* fine or forfeiture …, unless the *indictment or information*" was filed within two years, statute was construed to bar actions of debt qui tam: otherwise "a distinct member of the sentence … would be rendered almost totally useless"). Here, the relator received notice and took its opportunity to be heard. Once these had been accomplished, that should have been the end of the case.

This conclusion may seem counterintuitive. The law does not require the doing of a useless thing. *Mashi v. I.N.S.*, 585 F.2d 1309, 1314 (5th Cir. 1978). What, then, is the purpose of the statute's additional process if the government's litigation right is absolute and there is no substantive standard to apply? Congress sometimes demands that parties to a nascent legal dispute simply "communicate in some way" to attempt to resolve the dispute without court action, and there the judicial role is confined to ensuring that the communication has in fact taken place on the terms specified by statute. *Mach Mining, LLC v. E.E.O.C.*, 575 U.S. 480, 494 (2015) (Title VII conciliation); cf. Fed. R. Civ. P. 26(c)(1) (parties must confer or attempt to confer before seeking court order on discovery dispute); Fed. R. Civ. P. 37(a)(1) (same). In such cases, however, the court is not called upon to serve as a mere convening authority—"and perhaps," as the district judge put it here, "serve you some donuts and coffee"—while the parties carry on an essentially private conversation in its presence. Like the district court, we find unpersuasive *Swift*'s suggestion that "the function of a hearing when the relator requests one is simply to give the relator a formal opportunity to convince the government not to end the case." 318 F.3d at 253.

Not every case, though, will be like this one. For example, if the conditions of Rule 41(a)(1) do not apply, "an action may be dismissed at the plaintiff's request only by court order, on terms that the court considers proper." Fed. R. Civ. P. 41(a)(2). Thus, if the government's chance to serve notice of dismissal has passed, see Fed. R. Civ. P. 41(a)(1)(A)(i), and the relator by hypothesis refuses to agree to dismissal, see Fed. R. Civ. P. 41(a)(1)(A)(ii), then a hearing under § 3730(c)(2)(A) could serve to air what terms of dismissal are "proper." Cf. *Swift*, 318 F.3d at 252–53.

Further, there are always background constraints on executive action, even in the quasi-prosecutorial context of qui tam actions and the decisions to dismiss them. *Heckler v. Chaney*, 470 U.S. 821 (1985), cited by the government here, is not to the contrary. *Heckler* held that an administrative agency's decision not to take certain "investigatory and enforcement actions" had been "committed to agency discretion by law" and was thus not subject to judicial review under the Administrative Procedure Act. 470 U.S. at 824, 838; see 5 U.S.C. § 701(a)(2).

Heckler is an imperfect fit for the False Claims Act because the Court relied in part on the fact that "when an agency refuses to act it generally does not exercise its coercive power over an individual's liberty or property rights." 470 U.S. at 832 (emphasis omitted). That is not the case when the government dismisses a relator's action under the False Claims Act because "the statute gives the relator himself an interest *in the lawsuit*" as well as a partial assignment of the government's damages. *Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772, 773 (2000); cf. *Logan v. Zimmerman Brush Co.*, 455 U.S. 422, 428–430 (1982) (Due Process Clause

protects causes of action); *id.* at 438 (Blackmun, J., concurring for four Justices) (same for Equal Protection Clause).

More important, *Heckler* reserved decision on what result would follow if there were a "colorable claim … that the agency's refusal to institute proceedings violated any constitutional rights" of the plaintiffs. 470 U.S. at 838. Its accompanying citation to *Yick Wo v. Hopkins* suggests the limits of executive nonenforcement decisions:

> [E]nforcing these notices may … bring ruin to … those against whom they are directed, while others, from whom they are withheld, may be actually benefited by what is thus done to their neighbors; and, when we remember that this action of non-action may proceed from enmity or prejudice, from partisan zeal or animosity, from favoritism and other improper influences …, it becomes unnecessary to suggest … the injustice capable of being wrought.

118 U.S. 356, 373 (1886); see *Heckler*, 470 U.S. at 839 (Brennan, J., concurring) ("It is possible to imagine other nonenforcement decisions made for entirely illegitimate reasons, for example, … in return for a bribe.").

In this light, *Sequoia Orange* may be read to hold no more than that the government's § 3730(c)(2)(A) dismissal may not violate the substantive component of the Due Process Clause. Demanding "no greater justification … than is mandated by the Constitution itself," *Sequoia Orange* equated its rational-relation test to the test used to determine "whether executive action violates substantive due process." 151 F.3d at 1145, 1146. *Swift* rejected as contrary to *Heckler* the *Sequoia Orange*

point that "arbitrary or irrational" decisions not to prosecute could violate due process, 318 F.3d at 253, but *Heckler* does not warrant such a strong statement. See *Yick Wo*, 118 U.S. at 370 (no room "for the play and action of purely personal and arbitrary power"). In arguing a similar case before the Ninth Circuit,[4] the government suggested that its § 3730(c)(2)(A) dismissal may not violate the Equal Protection Clause. See *Oyler v. Boles*, 368 U.S. 448, 456 (1962). Before this court, the government suggested, and even *Swift* entertained the possibility of, review for fraud on the court. See 318 F.3d at 253. We agree in principle with both suggestions, though we hope that these generous limits would be breached rarely if ever. We say only that in exceptional cases they could supply grist for the hearing under § 3730(c)(2)(A).

Not in this case, though. Wherever the limits of the government's power lie, this case is not close to them. At bottom, the district court faulted the government for having failed to make a particularized dollar-figure estimate of the potential costs and benefits of CIMZNHCA's lawsuit, as opposed to the more general review of the Venari companies' activities undertaken and described by the government. No constitutional or statutory directive imposes such a requirement. None is found in the False Claims Act. The government is not required to justify its litigation decisions in this way, as though it had to show "reasoned decisionmaking" as a matter of administrative law, as in, for example, *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 51–52 (1983).

We must disagree with the suggestion that the government's decision here fell short of the bare rationality standard

[4] See n.2, supra.

borrowed by *Sequoia Orange* from substantive due process cases. "[T]he Due Process Clause was intended to prevent government officials from abusing their power, or employing it as an instrument of oppression," and "only the most egregious official conduct can be said to be arbitrary in the constitutional sense." *County of Sacramento v. Lewis*, 523 U.S. 833, 846 (1998) (internal quotation marks and alterations omitted); see also *Yick Wo*, 118 U.S. at 369–70 ("[O]ur institutions of government … do not mean to leave room for the play and action of purely personal and arbitrary power."). Executive action is not due process of law when it "shocks the conscience;" when it "offend[s] even hardened sensibilities;" or when it is "too close to the rack and the screw to permit of constitutional differentiation." *Rochin v. California*, 342 U.S. 165, 172 (1952).

The government proposed to terminate this suit in part because, across nine cited agency guidances, advisory opinions, and final rulemakings, it has consistently held that the conduct complained of is probably lawful. Not only lawful, but beneficial to patients and the public. As the government argued in the district court, "These relators"—created as investment vehicles for financial speculators—"should not be permitted to indiscriminately advance claims on behalf of the government against an entire industry that would undermine … practices the federal government has determined are … appropriate and beneficial to federal healthcare programs and their beneficiaries." This is not government irrationality. It oppresses no one and shocks no one's conscience.[5]

[5] At the hearing, the government cited the following: Medicare and State Health Care Programs, HHS Final Rule, 81 Fed. Reg. 88,368 (Dec. 7, 2016); Special Fraud Alert, HHS Notice, 79 Fed. Reg. 40,115 (July 11, 2014); Medicare and State Health Care Programs, HHS Final Rule, 78 Fed. Reg. 79,202

Accordingly, where the government's conduct does not bump up against the Rules, the statute, or the Constitution, the notice and hearing under § 3730(c)(2)(A) serve no great purpose. But that will not be true in every case. Our reading of § 3730(c)(2)(A) does not render its process futile as a general matter. Rather, this particular relator simply had no substantive case to make at the hearing to which the statute entitled it. Whenever a party has the right to invoke the court's aid, it has the obligation to do so with at least a non-frivolous expectation of relief under the governing substantive law. Fed. R. Civ. P. 11(b). That is not always possible, but that does not make the right meaningless.

In any event, the danger that the § 3730(c)(2)(A) hearing may often serve little purpose does not justify imposing on the government in each case the burden of satisfying *Sequoia Orange*'s "two-step test" before the burden is put back on the relator to show unlawful executive conduct. 151 F.3d at 1145; cf. *United States v. Armstrong*, 517 U.S. 456, 464 (1996) ("in the absence of clear evidence to the contrary," courts presume regularity of prosecutorial decision-making). Nor does a Senate report on an unenacted version of the 1986 amendments frame a proper standard for § 3730(c)(2)(A) dismissals where Congress itself has supplied none in the enacted statute. See *Swift*, 318 F.3d at 253, discussing S. Rep. No. 99-345, at 26

(Dec. 27, 2013); OIG Advisory Op. No. 12-20, HHS, 2012 WL 7148096 (Dec. 12, 2012); OIG Advisory Op. No. 12-10, HHS, 2012 WL 4753657 (Aug. 23, 2012); OIG Compliance Program Guidance for Pharmaceutical Manufacturers, HHS Notice, 68 Fed. Reg. 23,731 (May 5, 2003); OIG Advisory Op. No. 00-10, HHS, 2000 WL 35747420 (Dec. 15, 2000); Publication of OIG Special Fraud Alerts, HHS Notice, 59 Fed. Reg. 65,372 (Dec. 19, 1994); Medicare and State Health Care Programs, HHS Final Rule, 56 Fed. Reg. 35,952 (July 29, 1991).

(1986). If Congress wishes to require some extra-constitutional minimum of fairness, reasonableness, or adequacy of the government's decision under § 3730(c)(2)(A), it will need to say so. See § 3730(c)(2)(B).

Two final matters relating to § 3730(c)(3). First, because we have construed the government's motion to dismiss as a motion to intervene and dismiss for both jurisdictional and merits purposes, it might be thought proper to remand the case for the district court to consider the government's "good cause" to intervene under § 3730(c)(3). We see no need for a further hearing here because the proper outcome is clear. In light of the government's unrestricted substantive right under Rule 41(a) and the absence of countervailing factors, such as fairness to the relator or conservation of judicial resources (likely not factors in any case at an early enough stage for Rule 41(a)(1)(A)(i) to apply), we see no basis for denying intervention here. A denial would be an abuse of discretion, so we need not remand for that purpose. *United States v. Ford*, 627 F.2d 807, 811 (7th Cir. 1980).

Second, because § 3730(c)(3) instructs the district court not to "limit[] the status and rights" of the relator when permitting the government to intervene, it might be argued that § 3730(c)(1) and (2) do not apply when the government intervenes under § 3730(c)(3). Presumably in such cases the government would be treated as an ordinary Rule 24(b) intervenor-plaintiff with the same rights as the original plaintiff. See 7C Charles Alan Wright, Arthur R. Miller, et al., *Federal Practice and Procedure* § 1920 (3d ed. 1998 & supp. 2019). But intervention is already given to the government on basically identical terms under Rule 24(b)(2). There is no need to construe § 3730(c)(3) so that it would add nothing. We find it unlikely

that Congress meant to introduce a new configuration of the government-relator relationship (that is, as co-equal plaintiffs) in an ancillary provision without otherwise providing for its terms in § 3730(c). See *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (Congress does not hide "elephants in mouseholes"). The better reading is that § 3730(c)(3) instructs the district court not to limit the relator's "status and rights" as they are defined by §§ 3730(c)(1) and (2). Thus, the government cannot gain an advantage by intervening after the seal period; the relator cannot gain an advantage by engaging in gamesmanship or delay during the seal period.

The decision of the district court is REVERSED and the case is REMANDED with instructions to enter judgment for the defendants on the relator's claims under the False Claims Act, dismissing those claims with prejudice as to the relator and without prejudice as to the government.

Appendix: 31 U.S.C. § 3730(b)–(c)

(b) Actions by Private Persons.—(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the Parties to Qui Tam Actions.—(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court

may, in its discretion, impose limitations on the person's participation, such as—

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court

may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

SCUDDER, *Circuit Judge*, concurring in the judgment. I agree with the majority's analysis of the jurisdictional question and bottom-line conclusion. But because I prefer to decide the government's challenge to the district court's denial of its motion to dismiss on narrower grounds, I concur in the judgment.

The majority opinion rightly observes that Section 3730(c)(2)(A) of the False Claim Act is an odd provision. It is strange to grant the government broad dismissal authority but then condition any dismissal on the district court holding a hearing (to allow a relator to voice objections) that leads to no judicial review. The oddity of that outcome contributes to the difficulty of landing on the right answer to the question of statutory construction analyzed in depth in the majority opinion.

What I am more confident saying is that this appeal does not require us to answer the question. We can (and should) resolve this case without deciding whether the D.C. Circuit got it right in holding that Section 3730(c)(2)(A) confers unfettered discretion upon the government to dismiss a *qui tam* action or instead whether the Ninth Circuit has the better end of the reasoning in requiring a dismissal decision to survive rational basis review. Compare *Swift v. United States*, 318 F.3d 250 (D.C. Cir. 2003), with *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp.*, 151 F.3d 1139 (9th Cir. 1998). Even under the Ninth Circuit's standard, the government's dismissal request easily satisfied rational basis review, and the district court committed error concluding otherwise. See *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 314–15 (1993) (underscoring that the rational basis standard requires "a paradigm of judicial restraint" and indeed ruling

out "every conceivable basis" otherwise supporting the challenged measure).

I would stop there. While the majority opinion contains a sophisticated discussion of whether principles of constitutional avoidance should play any role in a question of statutory interpretation under the False Claims Act, I would rather confront that question in a case where the outcome hinged on the answer. In my respectful view, the narrower ground is the best ground to stand on to resolve this appeal.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, et al., ex rel. CIMZNHCA, LLC,	)	
Plaintiff,	)	
vs.	)	**Case No. 17-cv-765 –SMY-MAB**
UCB, INC., RXC ACQUISITION COMPANY d/b/a RX CROSSROADS, OMNICARE, INC., and CVS HEALTH CORPORATION,	)	
Defendants.	)	

MEMORANDUM AND ORDER

YANDLE, District Judge:

This matter is before the Court for consideration of the United States of America's (the "Government") Motion to Alter Judgment (Doc. 85). The Government, arguing the Court misapplied the Ninth Circuit's decision in *United States ex rel. Sequoia Orange Co. v. Baird-Neece Packing Corp*., 151 F.3d 1139 (9th Cir. 1998), seeks reconsideration of the Court's Order denying its Motion to

Dismiss (Doc. 83). Relator filed a Response in opposition to the Motion (Doc. 86).

F.R.C.P. 59(e) provides a basis for relief when a party challenges the Court's application of the law to the facts of the case. *See Osterneck v. Ernst & Whinney*, 489 U.S. 169, 174-76 (1989). A Rule 59(e) motion will be granted upon a showing of either evidence in the record that clearly establishes a manifest error of law or fact or newly discovered evidence not previously available. *Sigsworth v. City of Aurora, Ill.*, 487 F.3d 506, 511-12 (7th Cir. 2007); *Romo v. Gulf Stream Coach, Inc.*, 250 F.3d 1119, 1121 n.3 (7th Cir. 2001).

"Manifest error" is not demonstrated merely by the disappointment of the losing party. *Sedrak v. Callahan*, 987 F.Supp. 1063, 1069 (N.D. Ill. 1997). Rather, it is a court's "wholesale disregard, misapplication, or failure to recognize controlling precedent." *Id.* The Government contends this Court misapplied *Sequoia Orange* by evaluating the Government's stated reasons for dismissal rather than simply accepting them. This argument, however, is premised on the standard adopted by the D.C. Circuit Court in *Swift v. United States*, 318 F.3d 250, 252 (2003) – a standard this Court has rejected.

Under *Sequoia Orange*, courts do not blindly accept the Government's stated reasons for dismissal, but instead, conduct a judicial a limited judicial review to ensure the Government's decision to dismiss is not fraudulent, arbitrary or an abuse of power. The appropriate analysis involves a determination of the existence of a valid governmental purpose and a rational relationship between dismissal and the accomplishment of that purpose. *Sequoia Orange Co.*, 151 F.3d at 1145.

Here, the Government asserted that its move to dismiss was rationally related to its legitimate interest in avoiding the expenditure of substantial resources on a case it believes to be without merit and contrary to important policy prerogatives of its healthcare programs. The Government's claim that it reached this conclusion after having conducted an extensive investigation was belied by the parties' briefing and the evidence adduced during the evidentiary hearing, which showed that while the Government collectively and generally investigated the eleven *qui tam* cases filed by the Relator, its investigation into the claims specifically asserted in this case was minimal and it conducted no meaningful cost-benefit analysis.

Nevertheless, the Government argues that this Court "…erred in substituting its judgment for the government's in determining how the government should apply its limited resources, and in concluding that the government needed to conduct further investigation before seeking to dismiss this action to preserve those resources." (Doc. 85, pp.2-3). But this is an inaccurate depiction of the review the Court actually conducted. The Court did not concern itself with how the Government expends its resources. Rather, consistent with *Sequoia Orange*, it tested the Government's stated reasons for seeking dismissal against the facts and evidence presented and concluded that the record simply did not support a rational relationship between the Government's identified cost and policy considerations and dismissal of this *qui tam* action.

There is also no newly discovered evidence supporting the Government's Motion. The consideration of newly discovered evidence requires a showing by the moving party that it did not know and reasonably could not have discovered with reasonable diligence the evidence proffered. *See Caisse Nationale de Credit Agricole v. CBI Industries, Inc.*, 90 F.3d 1264, 1269 (7th Cir. 1996). Apparently recognizing its failure to satisfy the *Sequoia Orange* standard, the Government attached additional exhibits to its Motion

– two Declarations by Department of Justice Attorneys and the Settlement Agreement from an unrelated *qui tam* action against Novo Nordisk (Docs. 85-1, 85-2). The information contained in these exhibits was obviously available to the Government prior to this Court's ruling on the Motion to Dismiss. As such, it does not constitute newly discovered evidence and may not be properly considered at this juncture.

For the foregoing reasons, this Court is satisfied that it made no errors of law or fact and that its ruling denying the Government's Motion to Dismiss is correct. Accordingly, the Motion to Alter Judgment (Doc. 85) is **DENIED** in its entirety.

IT IS SO ORDERED.

DATED: June 7, 2019

STACI M. YANDLE
United States District Judge

APPENDIX C

United States Court of Appeals

For the Seventh Circuit
Chicago, Illinois 60604

September 17, 2020

Before

ILANA DIAMOND ROVNER, *Circuit Judge*

DAVID F. HAMILTON, *Circuit Judge*

MICHAEL Y. SCUDDER, *Circuit Judge*

No. 19-2273

UNITED STATES OF AMERICA ex rel. CIMZNHCA, LLC, *Plaintiff-Appellee*, *v*. UCB, INC., et al., *Defendants*,	Appeal from the United States District Court for the Southern District of Illinois. No. 3:17-cv-00765-SMY-MAB **Staci M. Yandle**, *Judge.*

APPEAL OF:

UNITED STATES OF AMERICA,
Appellant.

O R D E R

On consideration of plaintiff-relator's petition for panel rehearing and rehearing en banc, filed August 31, 2020, no judge in active service has requested a vote on the petition for rehearing en banc, and all judges on the original panel have voted to deny the petition for panel rehearing.

Accordingly, the petition for panel rehearing and rehearing en banc filed by plaintiff-relator is DENIED.

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

UNITED STATES OF AMERICA, et al. ex rel. CIMZNHCA, LLC,	)	
Plaintiff,	)	Case No.: 3:17-cv-00765-SMY-DGW
v.	)	
UCB, INC.; RXC ACQUISITION COMPANY d/b/a RX CROSSROADS; OMNICARE, INC.; and CVS HEALTH CORPORATION,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT AND JURY DEMAND

PRELIMINARY STATEMENT

Plaintiff-Relator CIMZNHCA, LLC ("CIMZNHCA" or "Relator"), through its undersigned attorneys, alleges, based upon personal knowledge, relevant documents, investigations and information and belief, as follows:

1. This is a civil action brought against Defendant UCB, Inc. ("UCB"), and Defendants RXC Acquisition Company

(*d/b/a* RXCrossroads), Omnicare, Inc., and CVS Health Corporation (collectively referred to as "RXC") on behalf of the Government under the False Claims Act, 31 U.S.C. §§ 3729-3733 (the "False Claims Act" or "FCA) and the false claims acts of the respective Plaintiff States[1] to recover treble damages sustained by, and civil penalties and restitution owed to, the United States Government and

[1] The state statues are the: (1) California False Claims Act, Cal. Gov't Code §§ 12650 – 12656; (2) Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 4-310; (3) Connecticut False Claims and Other Prohibited Acts Under State-Administered Health or Human Services Programs Act, Conn. Gen. Stat. Ann. §§ 4-274 – 289; (4) Delaware False Claims and Reporting Act, Del. C. Ann. tit. 6, §§ 1201 – 1211; (5) District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012, D.C. Code Ann. §§ 2-381.01 – 381.10; (6) Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092; (7) Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 4-168.6; (8) Hawaii False Claims to the State Act, Haw. Rev. Stat. Ann. §§ 661-21 – 31; (9) Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8; (10) Indiana False Claims and Whistleblower Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5.5-18; (11) Iowa False Claims Act, Iowa Code Ann. §§ 685.1 – 685.7; (12) Louisiana Medical Assistance Programs Integrity Law, La. Stat. Ann. §§ 437.1 – 440.16; (13) Massachusetts False Claims Law, Mass. Gen. Laws Ann. ch. 12, §§ 5A – 5O; (14) Michigan Medicaid False Claim Act, Mich. Comp. Laws Ann. §§ 400.601 – 615; (15) Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 16; (16) Montana False Claims Act, Mont. Code. Ann. §§ 17-8-401 – 416; (17) Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250; (18) New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 32C-18; (19) New Mexico Medicaid False Claims Act, N.M. Stat. Ann.§§ 27-14-1 – 14-15; (20) New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 – 9-14; (21) New York False Claims Act, N.Y. Fin. Law §§ 187 – 194; (22) North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 618; (23) Oklahoma Medicaid False Claims Act, Okl. Stat. Ann. tit. 63, §§ 5053 – 5054; (24) Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9; (25) Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 108; (26) Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 – 185; (27) Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132; (28) Virginia Fraud Against Tax Payers Act, Va. Code Ann. §§ 8.01-216.1 – 216.19; and (29) Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130.

the respective state governments as a result of two intertwined, unlawful drug marketing schemes.

2. Since at least 2011, through the implementation of two different schemes, UCB and RXC have provided remuneration in the form of free services to prescribing providers in order to induce those providers to prescribe UCB's drug, Cimzia, to patients—a more typical unlawful "quid pro quo" kickback scheme. As a result of these schemes, pharmacies have submitted and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in improper reimbursements. These schemes are ongoing.

3. UCB and RXC's schemes undermine the independent decision making of providers, an important element in Government Healthcare Program coverage policy. The providers prescribing UCB's drug, Cimzia, did not necessarily do so because they believed, based on their medical judgment, review of peer-reviewed medical literature, or discussion with their colleagues, that the drug would help their patients. Rather, UCB's drug, Cimzia, was and often is supplied because UCB and RXC actively and improperly pursued and enticed providers with free services and other forms of remuneration.

4. As a result of these schemes, pharmacies have submitted and continue to submit claims to Medicare and Medicaid that were tainted by kickbacks, causing these programs to pay tens of millions of dollars in improper reimbursements.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the claims Relator brings on behalf of the United States under the FCA pursuant to 28 U.S.C. §§ 1331 and 1345. This Court has supplemental jurisdiction over the claims asserted under the laws of the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the Commonwealth of Virginia, and the State of Washington, pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b).

6. This Court may exercise personal jurisdiction over UCB and RXC and venue is proper in this District pursuant to 31 U.S.C. § 3732(a) as well as 28 U.S.C. §§ 1391(b) and 1391(c) because UCB and RXC each transact business in this District and, in furtherance of its fraudulent kickback schemes, caused to be submitted or conspired to submit false claims in this District.

7. Relator has direct and independent knowledge on which the allegations herein are based, is an original source of this information, and has voluntarily provided the information to the United States before filing this action based on the information known to Relator. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure unknown to Relator, Relator is an original source under 31 U.S.C. § 3730(e)(4) and the applicable provisions of the respective State False Claims Act laws.

PARTIES

8. Relator CIMZNHCA, LLC ("CIMZNHCA") is a New Jersey-based entity formed to investigate and act as the Relator for the matters alleged herein.

9. Relator brings this action on behalf of the United States pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729 *et seq.*

10. Defendant UCB, Inc. ("UCB") is a human therapeutics company in the biotechnology industry. It conducts business throughout the United States, including the Southern District of Illinois, and in many other countries. Defendant UCB is incorporated in the State of Delaware and has its United States headquarters in Smyrna, Georgia with its principal place of business located at 1950 Lake Park Drive, Smyrna, Georgia 30080. Defendant UCB engages in the discovery, development, manufacture, and delivery of bio-therapeutics (e.g., prescription drugs) for various medical needs. Defendant UCB's drugs include the drug, Cimzia.

11. Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) is a Delaware corporation headquartered in Kentucky with its principal place of business located at 1901 Eastpoint Parkway, Louisville, Kentucky, 40223. In 2005, Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) was acquired by Defendant Omnicare, Inc. Later, in 2015, Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) and Defendant

Omnicare, Inc. were acquired by Defendant CVS Health Corporation. Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) provides and coordinates services between wholesale distributors, home health agencies, nurse educators, pharmacies, and health care product manufacturers, including UCB. It conducts business throughout the United States, including the Southern District of Illinois.

12. Defendant Omnicare, Inc. ("Omnicare") is a Delaware corporation headquartered in Cincinnati, Ohio with its principal place of business located at Omnicare, Inc. 900, Omnicare Center 201, East Fourth Street, Cincinnati Ohio, 45202. Defendant Omnicare purchased Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) in 2005. Defendant Omnicare is a wholly owned subsidiary of Defendant CVS Health Corporation and provides comprehensive pharmaceutical services to patients and providers across the United States, including the Southern District of Illinois.

13. Defendant CVS Health Corporation ("CVS") is Delaware corporation headquartered in Woonsocket, Rhode Island with its principal place of business located at One CVS Drive, Woonsocket, Rhode Island 02895. Defendant CVS acquired Defendant RXC Acquisition Company (*d/b/a* RXCrossroads) and

Defendant Omnicare in 2015. Defendant CVS is the largest pharmacy health care provider in the United States, with integrated offerings across the spectrum of pharmacy care. It conducts business throughout the United States, including the Southern District of Illinois.

14. Defendant RXC Acquisition Company (*d/b/a* RXCrossroads), Defendant Omnicare, and Defendant CVS are collectively referred to herein as "Defendant RXC" and/or "RXC."

15. Defendant UCB and Defendant RXC are collectively referred to herein as "Defendants."

STATUTORY BACKGROUND

A. The False Claims Act

16. The FCA establishes treble damages liability to the United States for any individual or entity that:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> knowingly makes or uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
>
> conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

31 U.S.C. § 3729(a)(1)(A)-(C). Within the meaning of the FCA, "knowing" is defined to include reckless disregard and

deliberate indifference. *Id*.

17. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim. The civil penalties range from (a) $5,500 to $11,000 for violations that occurred prior to November 2, 2015; (b) $10,781 to $21,563 for violations that occurred from November 3, 2015 to February 2, 2017; and (c) $10,957 to $21,916 for violations that occurred after February 3, 2017. *See, e.g.*, 64 Fed. Reg. 47099, 47103 (1999).

B. The Anti-Kickback Statute

18. The Anti-Kickback Statute, 42 U.S.C. §1320a-7b *et seq.* ("AKS"), states as follows in relevant part:

> (b) Illegal remunerations
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return

for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or

> imprisoned for not more than five years, or both.

19. For purposes of the AKS, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly. Importantly, the AKS has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for referral of services or to induce further referrals.

20. The AKS is designed to, among other things, ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

21. In order to ensure compliance, every federally-funded health care program requires every provider or supplier to ensure compliance with the provisions of the AKS and other federal laws governing the provision of health care services in the United States.

22. The AKS was amended in March 2010 as part of the Patient Protection and Affordable Care Act ("PPACA"), which clarified that all claims resulting from a violation of the AKS are also a violation of the FCA. 42 U.S.C. § 1320a-7(b)(g). The PPACA also amended the Social Security Act's "intent requirement" to make

clear that violations of its anti-kickback provisions, like violations of the FCA, may occur even if an individual does "not have actual knowledge" or "specific intent to commit a violation." 18 U.S.C. § 1347(b).

23. Knowingly providing kickbacks to providers to induce them to prescribe a drug (or to influence provider prescriptions) for individuals who seek reimbursement for the drug from a federal health care program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the government as if in compliance with these laws, violates the FCA.

24. The Balanced Budget Act of 1997 amended the AKS to include administrative civil penalties of $50,000 for each violation, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a portion of that amount was offered, paid or received for a lawful purpose. *See* 42 U.S.C. § 1320a-7a(a).

25. The AKS contains statutory exceptions and certain regulatory "safe harbors" that exclude certain types of conduct from the reach of the statute. *See* 42 U.S.C. § 1320a-7b(b)(3). None of the statutory exceptions or regulatory safe harbors protect the

Defendants from liability for the conduct alleged herein. Compliance with the AKS is a condition of payment under federal health care programs.

AFFECTED HEALTH PROGRAMS

26. Generally, when a physician prescribes a drug, a patient is provided with a prescription that is then filled at a pharmacy. The pharmacy then submits the claim for payment to the relevant federal health care program(s) for reimbursement.

27. In certain circumstances, a federal program may also have pharmacy facilities that directly dispense prescription drugs. In such cases, the federal health care program purchases the drug directly rather than reimbursing the pharmacy.

A. Medicare

28. Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are sixty-five years old or older or disabled. *See* 42 U.S.C. §§ 1395, *et seq.* ("Medicare Program"). Part D of the Medicare Program was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, to provide prescription drug benefits for Medicare beneficiaries. Medicare Part D became effective January 1, 2006. All persons enrolled in

Medicare Part A and/or Medicare Part B are eligible to enroll in a prescription drug plan under Part D. The United States Department of Health and Human Services ("HHS"), through its component agency, the Centers for Medicare and Medicaid Services ("CMS"), contracts with private companies (or "Part D sponsors") to administer prescription drug plans. Such companies are regulated and subsidized by CMS pursuant to one-year, annually renewable contracts. Part D sponsors enter into contracts with many pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

29. Generally, after a physician writes a prescription for a patient who is a Medicare beneficiary, that patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses drugs to the Medicare beneficiary, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor, sometimes through the sponsor's pharmacy benefit manager ("PBM"). The pharmacy receives reimbursement from the sponsor (or PBM) for the portion of the drug cost not paid by the beneficiary. The Part D sponsor is then required to submit to CMS an electronic notification of the drug dispensing event, referred to as the Prescription Drug Event ("PDE"), which contains data regarding the prescription

claim, including the service provider of the drug, the prescriber of the drug, the quantity dispensed, the amount it has paid to the pharmacy, and whether the drug is covered under the Medicare Part D benefit.

30. Payments to a Part D Plan sponsor are conditioned on the provision of information to CMS that is necessary for CMS to administer the Part D program and make payments to the Part D Plan sponsor for qualified drug coverage. 42 C.F.R. § 423.322. CMS's instructions for the submission of Part D prescription PDE claims data state that "information . . . necessary to carry out this subpart" includes the data elements of a PDE. PDE records are an integral part of the process that enables CMS to administer the Part D benefit. Each PDE that is submitted to CMS is a summary record that documents the final adjudication of a dispensing event based upon claims received from pharmacies and serves as the request for payment for each individual prescription submitted to Medicare under the Part D program.

31. CMS gives each Part D sponsor advance monthly payments consisting of the Part D sponsor plan's direct subsidy per enrollee (which is based on a standardized bid made by the Part D sponsor), estimated reinsurance subsidies for catastrophic coverage,

and estimated low income subsidies. 42 C.F.R. §§ 423.315, 423.329. At the end of the payment year, CMS reconciles the advance payments paid to each Part D sponsor with the actual costs the sponsor has incurred. In this reconciliation process, CMS uses the PDE claims data it has received from the Part D sponsor during the prior payment year to calculate the costs the Part D sponsor has actually incurred for prescriptions filled by Medicare beneficiaries under Part D. If CMS underpaid the sponsor for low-income subsidies or reinsurance costs, it will make up the difference. If CMS overpaid the sponsor for low-income subsidies or reinsurance costs, it will recoup the overpayment from the sponsor. After CMS reconciles a plan's low-income subsidy and reinsurance costs, it then determines risk-sharing amounts owed by the plan to CMS or by CMS to the plan related to the plan's direct subsidy bid. Risk-sharing amounts involve calculations based on whether and to what degree a plan's allowable costs exceeded or fell below a target amount for the plan by certain threshold percentages. 42 C.F.R.§ 423.336.

32. CMS's payments to the Part D sponsor come from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R.§

423.315(a).

33. In order to receive Part D funds from CMS, Part D Plan sponsors, as well as their authorized agents, employees, and contractors (including pharmacies), are required to comply with all applicable federal laws, regulations, and CMS instructions.

34. By statute, all contracts between a Part D Plan sponsor and HHS must include a provision whereby the Plan sponsor agrees to comply with the applicable requirements and standards of the Part D program as well as the terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112.

35. Medicare Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse, including the FCA and AKS. 42 C.F.R.§ 423.505(h)(l).

36. In accordance with these express statutory and regulatory requirements, all contracts entered into between CMS and Plan D Plan sponsors from 2006 through the present include a provision in which the sponsor "agrees to comply with . . . federal laws and regulations designed to prevent . . . fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. §§ 3729, *et seq*.), and

the anti-kickback statute (§ 1127B(b) of the Act)."

37. CMS regulations further require that all contracts between Part D Plan sponsors and downstream entities, such as pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

38. A Part D Plan sponsor also is required by federal regulation to certify to the accuracy, completeness and truthfulness of the PDE claims data submitted to CMS. Specifically, the relevant regulatory provision, entitled "Certification of data that determine payment", provides in relevant part:

> (1) General rule. As a condition for receiving a monthly payment under subpart G of this part (or for fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may

include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.

(2) Certification of enrollment and payment information. The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that each enrollee for whom the organization is requesting payment is validly enrolled in a program offered by the organization and the information CMS relies on in determining payment is accurate, complete, and truthful and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

(3) Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits under § 423.329(b)(3) (or for fallback entities, under§ 423.87l(f)) are accurate, complete, and truthful and acknowledge that the claims data will

> be used for the purpose of obtaining Federal reimbursement.

42 C.F.R. § 423.505(k).

39. Compliance with the regulatory requirement that the PDE data submitted to CMS is "true, accurate, and complete" is a condition of payment under the Medicare Part D program to the extent that it involves a violation of the AKS.

40. In accordance with this regulatory requirement, since the Part D program began, Medicare has required each Part D Plan sponsor to sign annually an Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor ("Attestation"). This Attestation states:

> Pursuant to the contract(s) between the Centers for Medicare & Medicaid Services (CMS) and the Medicare Part D Organization(s) listed above, hereafter referred to as the Part D Organization, governing the operation of the contract numbers listed above, the Part D Organization hereby makes the following attestations concerning CMS payments to the Part D Organization:
>
> The Part D Organization attests that based on its best knowledge, information, and belief, the final Prescription Drug Event

(PDE) data that have been submitted to and accepted by CMS as of [date] with respect to the Part D plans offered under the above-stated contract(s) for the dates of service of January 1, [prior year] to December 31, [prior year], are accurate, complete, and truthful and reflect all retroactive adjustments of which the Part D organization has been informed by May 30, [current year]. In addition, the Part D Organization attests that based on best knowledge, information, and belief, the payments that have been made by the Part D organization for the claims summarized by the aforementioned PDE data were made in accordance with the coordination of benefits guidance in Chapter 14 of the Medicare Prescription Drug Benefit Manual and other applicable CMS guidance. The Part D Organization attests that based on its best knowledge, information, and belief as of the date(s) of last successful DIR [Direct and Indirect Remuneration Data] [prior year] data submission(s) via the Health Plan Management System (HPMS) as listed above, the final direct and indirect remuneration data submitted to CMS for the Part D plans offered under the above-stated contract(s) for the [prior] coverage year are accurate, complete, and truthful and fully conform to the

requirements in the Medicare Part D program regulations and the Final Medicare Part D DIR Reporting Requirements for [the prior year]. The Part D Organization also certifies that based on its best knowledge, information, and belief as of the date indicated below, all other required information provided to CMS to support the determination of allowable reinsurance and risk corridor costs for the Part D plans offered under the above-stated contract(s) is accurate, complete, and truthful. With regards to the information described in the above paragraphs, the Part D Organization attests that it has required all entities, contractors, or subcontractors, which have generated or submitted said information (PDE and DIR data) on the Part D Organization's behalf, to certify that this information is accurate, complete, and truthful based on its best knowledge, information, and belief. In addition, the Part D Organization attests that it will maintain records and documentation supporting said information. The Part D Organization acknowledges that the information described in the above paragraphs will be used for the purposes of obtaining federal reimbursement and that misrepresentations or omissions in information provided to CMS may

> result in Federal civil action and/or criminal prosecution.

41. All approved Part D Plan sponsors who received payment under Medicare Part D in benefit years 2006 through the present date submitted these required Attestations in the same or similar format.

42. Medicare regulations further provide: "If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data and acknowledge that the claims data will be used for the purposes of obtaining Federal reimbursement." 42 C.F.R. § 423.505(k)(3).

43. Medicare also enters into agreements with physicians to establish the physician's eligibility to participate in the Medicare program. For the physician to be eligible for participation in the Medicare program, physicians must certify that they agree to comply with the Anti-Kickback Statute, among other federal health care laws. Specifically, on the Medicare enrollment form, CMS Form 855I, the "Certification Statement" that the medical provider signs states: "You MUST sign and date the certification statement

below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below." Those requirements include:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to me ... The Medicare laws, regulations and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity

B. Medicaid

44. Medicaid is a joint federal-state program created in 1965 that provides health care benefits for certain groups, primarily the poor and disabled. Each state administers a State Medicaid program. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum

criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A). While drug coverage is an optional benefit, the Medicaid programs of all states provide reimbursement for prescription drugs.

45. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least fifty percent and is as high as eighty-three percent. Federal funding under Medicaid is provided only when there is a corresponding state expenditure for a covered Medicaid service to a Medicaid recipient. The federal government pays to the state the statutorily established share of the "total amount expended ... as medical assistance under the State plan." 42U.S.C. § 1396b(a)(l).

46. The vast majority of states award contracts to private companies to evaluate and process claims for payment on behalf of Medicaid recipients. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid programs. Before the beginning of each calendar quarter, each state submits to CMS an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the

quarterly estimate as necessary and determines the amount of federal funding each state will be permitted to draw down as it incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims, including claims from pharmacies seeking payment for drugs, are presented for payment. After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount (to reconcile the estimated expenditures to actual expenditures). 42 C.F.R.§ 430.30.

47. Claims arising from illegal kickbacks are not authorized to be paid under state regulatory regimes. In fact, providers who participate in the Medicaid program must sign enrollment agreements with their states that certify compliance with the state and federal Medicaid requirements, including the AKS. Although there are variations among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all state and federal laws and Medicaid regulations in billing the state Medicaid program for services or supplies furnished.

48. Furthermore, in many states, Medicaid providers, including both physicians and pharmacies, must affirmatively

certify compliance with applicable federal and state laws and regulations.

49. For example, in Illinois, physicians and pharmacies must sign an "Agreement for Participation in the Illinois Medical Assistance Program," in which the provider certifies that it is in compliance with applicable federal and state laws and regulations.

C. TRICARE

50. TRICARE (formerly known as CHAMPUS), is part of the United States military's health care system, designed to maintain the health of active duty service personnel, provide health care during military operations, and offer health care to non-active duty beneficiaries, including dependents of active duty personnel, and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

51. TRICARE prescription drug benefits are provided

through three different programs: military treatment facility outpatient pharmacies, TRICARE network retail pharmacies, and TRICARE's mail order service. TRICARE contracts with a PBM to administer its retail and mail order pharmacy programs. In-addition, TRICARE beneficiaries can also pay out-of-pocket to fill prescriptions at non-network retail pharmacies and submit a claim for reimbursement directly with TRICARE's PBM. The claims process is different for each of these pharmaceutical programs.

52. When a TRICARE beneficiary brings a prescription to a TRICARE network retail pharmacy, for example, the pharmacy submits an electronic claim to the PBM for that prescription event. The PBM sends an electronic response to the pharmacy that confirms the beneficiary's TRICARE coverage, and, if the prescription claim is granted, informs the pharmacy of the calculated pharmacy reimbursement amount and the co-pay (if applicable) to be collected from the beneficiary. The pharmacy then collects the co-pay amount (if any) from the beneficiary and dispenses the medication. After a 10-day hold to ensure the prescription was picked up and not returned to the shelf by the pharmacy, the PBM sends a TRICARE Encounter Data ("TED") record electronically to TRICARE. The TED record includes information regarding the

prescription event, including the reimbursement amount to be paid to the dispensing pharmacy. TRICARE then authorizes the PBM to make payment to the pharmacy for the amount remaining (after co-pay) on the claim. The PBM sends the payment to the pharmacy. After the payment is made by the PBM's bank, the PBM's bank requests reimbursement from the Federal Reserve Bank ("FRB"). The FRB then transfers funds to the PBM's bank account.

53. If the prescription is filled at a non-network retail pharmacy, the beneficiary must pay the full price of the prescription to the pharmacist and file a claim for reimbursement on DD Form 2642, TRICARE DoD/CHAMPUS Medical Claim -- Patient's Request for Medical Payment ("Form 2642"). The Form 2642 is mailed to the PBM. As in the case of reimbursements under the retail pharmacy program, a TED record is created and sent to TRICARE. TRICARE then authorizes payment to the TRICARE beneficiary. Upon receiving that authorization, the PBM issues a check to the beneficiary, which is drawn on the PBM's bank account. TRICARE then reimburses the PBM in the same manner as it does under the retail pharmacy program, such that funds are transferred from the FRB to the PBM's bank account.

54. TRICARE beneficiaries can also fill prescriptions

through TRICARE's mail order pharmacy program as well. TRICARE beneficiaries submit prescriptions by mail, fax, or electronically to TRICARE's PBM, along with any co-pay (if applicable). TRICARE's PBM delivers the prescription to the beneficiary via free standard shipping. The medications dispensed through the mail order pharmacy program are filled from the PBM's existing inventory of pharmaceuticals. The PBM then requests replenishment pharmaceuticals from DOD's national prime vendor contracted by Defense Logistics Agency ("DLA"). DOD procures the pharmaceuticals through its national prime vendor and replenishes the PBM's inventory of pharmaceuticals after accumulated dispensing reach full package size amounts. The PBM then submits a TED record to TRICARE to obtain administrative fees in connection with that prescription event. DLA bills TRICARE directly for drug replenishment costs.

55. Pursuant to 38 U.S. C. § 8126, pharmaceutical manufacturers are required to enter into national contracts with the DOD pursuant to which the manufacturer makes available for procurement certain covered drugs at the Federal Ceiling Price (a price that is calculated as at least 24% less than the manufacturer's average price based on all sales to commercial customers through a

wholesaler or distributor). Pursuant to DOD's contract with its national prime vendor, the national prime vendor submits an invoice to the DOD for payment of pharmaceuticals supplied to the PBM in connection with the mail order pharmacy program, charging the DOD the price set by the contract awarded by the DOD to the drug manufacturer.

56. Since March 2003, TRICARE has contracted with a PBM, Express Scripts, Inc. ("ESI"), to administer TRICARE's mail order pharmacy programs. ESI has also administered TRICARE's retail pharmacy program since June 2004.

57. Similarly, TRICARE's military treatment facilities purchase medications through procurement contracts with third party pharmaceutical prime vendors. When a TRICARE beneficiary submits an outpatient prescription to a military treatment facility's outpatient pharmacy, the pharmacy purchases the medication from the prime vendor pursuant to an existing procurement contract, and the drug is then dispensed to the patient.

58. While some physicians enroll in the TRICARE program as network or· participating providers, any physician that is licensed, accredited and meets other standards of the medical community is authorized to provide services to TRICARE

beneficiaries. Physicians who are enrolled in the TRICARE network must expressly certify their compliance with TRICARE's regulations. Yet all providers that provide services to TRICARE beneficiaries, whether network providers or non-participating providers, are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R.§ 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

59. The statutes and regulations set forth above concerning Medicare, Medicaid, and TRICARE, when viewed together, state that healthcare providers must comply with the AKS in order for claims they cause to be submitted to these programs to be reimbursed. The claims submitted here for Cimzia violated the AKS in that these claims stemmed from prescriptions written by providers in exchange for bribes from Defendants while knowing that claims for reimbursement would be submitted to the above programs as a result. As such, and as more fully discussed below, the prescribing healthcare providers, expressly and impliedly,

falsely certified compliance with the conditions of payment for, at least, Medicare, Medicaid, and TRICARE.

60. In addition to falsely certifying compliance with the AKS, the healthcare providers referred to herein also falsely certified compliance with contractual provisions that were required conditions for payment.

61. As detailed herein, UCB devised and implemented schemes whereby it gave kickbacks to third party "educators" from RXC to induce providers to prescribe UCB's drug, Cimzia, and whereby Defendants provided free, in-kind support services to providers to induce those providers to prescribe Cimzia.

62. Knowingly paying kickbacks to induce physicians to prescribe a drug on-label or off-label (or to influence physician prescriptions) for individuals who seek reimbursement for the drug from a federal health care program or causing others to do so, while certifying compliance with the AKS (or while causing another to so certify), or billing the Government as if in compliance with these laws, violates the FCA and similar state False Claims Acts.

DEFENDANTS' FRAUDULENT SCHEMES

63. To unmask Defendants' unlawful conduct, Relator and its representatives conducted a rigorous, multi-part investigation

that included interviews of numerous individuals with knowledge of and involvement in the schemes. The specific individuals whom Relator interviewed have direct knowledge with respect to the matters set forth herein during its investigation include:

- Witness A[2] – a sales representative for UCB from approximately June 2008 to April 2015 who promoted and sold Cimzia to prescribers;

- Witness B – a territory case manager for RXCrossroads since December 2011 who is now a supervisor for territory case managers;

- Witness C – a nurse educator for RXCrossroads since May 2015 who provides nurse education services for Cimzia primarily in Colorado;

- Witness D – a nurse educator for RXCrossroads since approximately 2013 who provides nurse education services for Cimzia primarily in Florida;

- Witness E – a case manager for RXCrossroads from approximately 2012 to 2013 who provided support services for Cimzia;

- Witness F – a sales representative for UCB from approximately June 2007 to May 2015 who promoted and sold Cimzia to prescribers;

- Witness G – a nurse educator for RXCrossroads from approximately 2007 to 2013 who provided nurse education services for Cimzia primarily in Michigan.

64. Relator has also conducted data analytics using a

[2] Witness information will be provided during discovery subject to a confidentiality order.

private healthcare data vendor that aggregates both public and private healthcare data. Through this vendor, Relator has access to and can analyze Medicare Part D prescription claims data, which provides information on prescription drugs, including Cimzia, prescribed by individual physicians and other health care providers that are paid for under the Medicare Part D Prescription Drug Program. Relator also has aggregated additional data from various state Medicaid providers. These data sources give Relator significant insight into prescription drug utilization over a multi-year period.

65. Through the investigation, Relator discovered Defendants' unlawful schemes to induce healthcare providers to write prescriptions for Cimzia by providing tangible, valuable benefits to healthcare providers in exchange for writing Cimzia prescriptions.

66. Cimzia is a brand-name prescription drug primarily used for the treatment of Crohn's Disease. Cimzia has other indications as well, including rheumatoid arthritis.

67. UCB sought to incentivize disease care providers to choose UCB's drug, Cimzia, over competitors' drugs. UCB identified the unique and particular needs and challenges that

disease care providers faced in managing their practices and patients. Once these providers' needs and challenges were identified, UCB, through RXC, began offering these providers "solutions" to those needs and challenges if they prescribed UCB's drug.

68. In the first scheme, RXC contracted to provide UCB with a force of nurse educators for Cimzia. UCB's Cimzia nurse educators are health care professionals who possess training, knowledge and experience in disease management, pre-disease care, and disease prevention. A nurse educator certification is "practice based" and requires health care professionals to gain professional experience working in the field.

69. Certified nurse educators are recognized as specialty clinicians with particular training, education and experience in disease education and care. Not surprisingly, nurse educators are in particular demand for providers who care for disease patients. Many nurse educators are employed by primary care and specialty practices to work with disease patients. As clinicians with significant training, education and experience, nurse educators can command significant compensation in the healthcare workforce.

70. In the second scheme, UCB induced providers to

recommend its drug by offering and providing what is referred to as "reimbursement support" services through RXC, which included thousands of dollars of administrative services offered to providers for free.

71. Both of these schemes were design to induce providers to prescribe Cimzia, and UCB actively engages in and promotes these schemes. For example, one of UCB's area directors, Kurt Hughes, is "responsible for Managing seven (7) Area Business Specialists covering 23 States in the West;" "for In office Administration/injection of Cimzia to Gastroenterologists Rheumatologists for their Crohn's and Rheumatoid Arthritis patients;" and "for the corresponding benefits coverage, billing and coding of our in office injectable and coordination with MD and Practice Administrators and others responsible for the purchasing, coverage, billing and coding of our medicine" in the greater Denver area and the west coast region.

72. UCB designed and implemented these schemes to induce providers to prescribe Cimzia and increase its revenue. As one former Cimzia sales representative stated when he was discussing his messaging to providers, "you just find the patients and we'll get them on the drugs."

A. *Quid Pro Quo* 1—Free Clinicians for Referrals

73. Relator's research determined that most prescribers typically allocate between 10 to 15 minutes to see routine patients. However, some patients, such as those suffering from Crohn's disease and rheumatoid arthritis, often require additional office time, training, follow-up, and additional resources to manage their disease. For these reasons, prescribers often rely on the services of highly skilled nursing staff – often called "nurse educators" – to help manage and treat these patients. The cost associated with the use of a nurse educator is significant, often requiring an annual salary that can exceed $60,000 or an hourly wage that can exceed $40.00 per hour.

74. Recognizing the additional needs associated with these patients, UCB developed a scheme whereby it would offer these nurse educators to providers at no charge if they would prescribe UCB's drug, Cimzia.

75. Specifically, UCB began offering and then providing these providers the time, service and expertise of an RXC employed nurse educator both to help manage that providers' disease patients and to provide disease training to the providers' staff. Of course, in typical *quid pro quo* fashion, in order to be given these services

those providers would have to "support" (i.e., write prescriptions for) UCB's specific drug.

76. UCB's Cimzia nurse educator program is marketed using a branded term, "CIMplicity."[3] The CIMplicity website touts "Support made simple for *your practice* and your patients" (emphasis added) including "Nurse support" (i.e. Nurse Educators) and "Comprehensive reimbursement assistance" (i.e. reimbursement support services).[4] RXC also touts their "Field Force" of "Nurse Educators" on their website.[5]

77. Once trained and deployed, these nurse educators began to provide free education services to any provider who would prescribe UCB's Cimzia. The RXC nurse educators were successful in saving prescribers time, money and resources and, in many instances, resulted in receiving higher reimbursement rates associated with certain disease care metrics. Not surprisingly, UCB's Cimzia sales have increased every year.

78. Relator interviewed two nurse educators employed

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[3] CIMplicity, http://cimziahcp.com/patient-support, (last visited December 27, 2016)
[4] *Id.*
[5] RXC Educators, https://www.rxcrossroads.com/OmnicareSCG/RXCrossroads/field-force, (last visited December 27, 2016)

by RXCrossroads who provided services for Cimzia and both agreed that their services save providers time and money. One nurse educator for RXCrossroads has provided nursed education services for Cimzia since May 2015 primarily in Colorado. The other nurse educator for RXCrossroads provided nurse education services for Cimiza from from approximately 2007 to 2013 in Michigan.

79. Likewise, a former Cimzia sales representative noted that he would promote these services to providers as a "free resource." He went on to say that he would talk to providers about how nurses could "go in there and eliminate some of the administrative burden and take that off their plate…"

80. When discussing how the provider no longer has to take the time to educate the patient, one nurse educator went on to state,"…don't sales reps give people – like doctors like tickets to games and stuff? I feel like that's a kickback. I feel like that's part of it. I feel like that extra training is like just another freebie for a physician – not to have to do the training." This nurse educator specifically noted that "they're prescribing medication without having to do any other work and getting kickback."

81. UCB recognized that having its own nurse educator interact directly with patients also resulted in an increase in Cimzia

refills and, thus, an increase in the revenue that these refills would provide. One nurse educator who provided education services for Cimzia stated that "adherence is dollars for the pharmaceutical industry…If they're adherent, they're refilling. Every time they refill their prescription, that's more dollars in the pharmaceutical company's pockets."

82. Two former UCB sales representatives confirmed they promoted these nurse education services as part of their sales pitch and strongly agreed that being able to promote the nurse educators helped them be successful in promoting Cimzia to potential prescribers.

83. One of the former sales representatives noted that he viewed nurse educators as an "extension of [his] efforts" because it was another resource who was in tune with what was going on in the provider's office.

84. The other former sales representative explained that being able to provide nurse educators helped "downstream" in the process and gave one example of a nurse educator being able to convince a patient to continue using Cimzia when the patient may not have otherwise continued with the drug. He stated that having a nurse educator involved resulted in higher success rates of patients

getting on Cimzia and staying on Cimzia.

85. UCB providing educational and other services to providers in exchange for recommending its drug violates the AKS because it provides remuneration in the form of free nurse services to induce prescribers to prescribe UCB's drug. Prescribers receive a substantial benefit in utilizing these free nurse educators because they save time and money that they would have otherwise had to expend.

B. *Quid Pro Quo* 2—Free Reimbursement Experts for Referrals

86. UCB also induced providers to prescribe Cimzia by offering and providing what is referred to as "reimbursement support" services through RXC.

87. When a provider writes a prescription for Cimzia, a number of additional steps must be completed before the patient is able to "fill" the prescription at the pharmacy. These steps customarily include:

- Determining whether and to what extent the patient has prescription drug insurance benefits;
- Determining if the drug is on the formulary lists and, if so, the applicable tiers;

- Seeking a coverage determination for the drug from the patient's carrier;
- Determining the patient's co-pays and deductibles;
- Determining whether a patient may qualify for "co-pay" assistance or coupons;
- Appealing any denial of coverage or prior authorization;
- Determining the in-network pharmacy where the patient can have the drug filled;
  communicating this information to the patient; and
  managing the resultant paper trail.

88. These steps are time consuming, averaging roughly about 20 hours per week for a provider's office.[6] Completing these tasks requires the attention of the provider and/or the provider's staff, resulting in discrete economic costs to the provider.

89. For certain prescription drugs that are particularly expensive, like Cimzia, the provider's office must work with the patient's insurance carrier to obtain prior authorization for the drug. Prior authorization is the requirement that a prescriber obtain

[6] *See* Christopher P. Morley, David J. Badolato, John Hickner, and John W. Epling, *The Impact of Prior Authorization Requirements on Primary Care Physicians' Offices: Report of Two Parallel Network Studies*, J. Am. Board Fam. Med. (January-February 2013), Vol. 26 no. 1, at 93-95.

approval from the patient's health insurance plan before the drug can be dispensed by a pharmacy—or the patient may be required to pay for the medicine "out of pocket."

90. Because it entails advocacy on behalf of the patient, obtaining prior authorization is a responsibility that falls within the prescriber's duty of care.[7] Importantly, numerous states have enacted legislation that requires prescribers to obtain prior authorizations on behalf of the patients. *See, e.g.*, Ala. Medicaid Preferred Drug and Prior Authorization Program, Prior Authorization Criteria Instructions; Cal. Health and Safety Code, § 1367.241; 10 CCR 2505-10, § 8.017E; Delaware Health and Social Services General Policy, § 1.17; Florida Medicaid, Authorization Requirements Policy, §2-2.4.4 (June 2016); Georgia Dept. of Comm. Health Medicaid Fee-for-Service Pharmacy Prior Authorization Request Process Guide; Louisiana Medicaid Program

[7] *See* Getting Medical Pre-approval or Prior Authorization, *available at* https://www.cancer.org/treatment/finding-and-paying-for-treatment/understanding-health-insurance/managing-your-health-insurance/getting-medical-pre-approval-or-prior-authorization.html (noting that "Prior authorization is often used with expensive prescription drugs. It means that your doctor must explain that the drug is medically necessary before the insurance company will cover it. The company may want you to use a different medicine or try a different one before they will approve the one your doctor prescribes.").

Provider Manual, Chapter 37, § 37.5.5; Mass. Health Provider Manual, § 450.303; Mich. Dept. of Health and Human Servs., § 7.5; Minn. Statutes, § 62J.497, subd. 5; NY State Medicaid Program, Physician Prior Approval Guidelines; N.C. Dept. of Health and Human Servs., Prior Approval and Due Process; NJAC 10:51-1.14; Oregon Health Authority, Instructions for Submitting Prior Authorization Requests for Oregon Medicaid Providers (Aug. 2015); Pennsylvania Pharmacy Prior Authorization General Requirements; S.C. DHHS, Pharmacy Services Medicaid Provider Manual, § 2; Tenn. Medicaid Pharmacy Claims Submission Manual, § 7.6; Texas Admin. Code. Title 28, § 19.1820; Texas Admin. Code. Title 1 § 531.073; WV Health and Human Resources Bureau Manual, § 518.2.

91. Medicare, Medicaid, and TRICARE carriers also use the prior authorization process to contain costs associated with expensive medications. This is particularly true for products like Cimzia, which are expensive and come with a myriad of potential side-effects that may require other medications to manage. For such products, carriers routinely require prescribers to "make a case" of medical necessity and explain why a less expensive product is not an acceptable alternative. This process is designed to save taxpayer

dollars by ensuring that the more expensive medications are prescribed only when needed.

92. As a coalition of healthcare organizations led by the American Medical Association has recognized, coverage determinations, prior authorization, and appeals often entail "very manual, time-consuming processes . . . [that can] divert valuable and scarce resources away from direct patient care."[8] Further, industry research demonstrates that these tasks are time-consuming and costly for prescribers. For instance, a study of 12 primary care practices published in 2013 in The Journal of the American Board of Family Medicine concluded that "preauthorization is a measurable burden on physician and staff time."[9]

93. According to another study published in 2009 in Health Affairs, primary care prescribers spent a mean of 1.1 hours per week on authorization-related work, primary care nursing staff spent 13.1 hours, and primary care clerical staff spent 5.6 hours.[10]

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[8] *See Prior Authorization and Utilization Management Reform Principles*, *available at* https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf.

[9] *See* Morley, *supra* at 93.

[10] *See id.* at 95 (citing Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra, Theodore Karrison, Wendy Levinson, *What Does It Cost Physician Practices To Interact With*

The same study estimated that the overall cost to the healthcare system of all practice interactions with health plans, including authorizations, was between $23 billion and $31 billion annually.

94. Alternatively, if a prescriber does not wish to pay its own staff to carry out these administrative tasks, prescribers can outsource them to third-party commercial vendors for a fee. Numerous vendors provide these outsourcing services. As a study conducted by Deloitte on behalf of a large pharmaceutical company demonstrates, medical practices pay up to $98 per initial insurance verification, up to $75 for insurance re-verification, up to $111.82 for prior authorizations, and other à la carte fees.

Health Insurance Plans?, Health Affairs (July-August 2009), Vol. 28 no. 4, at 533-43).

Activities	Lash	McKesson	Covance	Incumbent Average
Re-verfication	$20.75	$75.00	$50.00	$41.53
Insurance Verification	$98.00	$75.00	$75.00	$88.50
Reimbursement Support - Rate Verification	$68.00	$65.00	$0.00	$62.52
Coding & Reimbursement Assistance	$20.75	$30.00	$12.45	$23.43
Claims Support and Appeals	$104.28	$125.00	$57.78	$108.45
Ad Hoc Support and Consulting	$100.00	$100.00	$1.00	$93.54
Co-Pay Card Program Administration	$1.00	$0.00	$1.00	$0.65
Field Reimbursement Services	$19,180.00	$10,000.00	$1.00	$14,736.15
Site Visit/ Telecon	$2,150.00	$100.00	$1.00	$1,296.80
General Inquiry	$20.75	$15.00	$12.45	$18.21
Injection Network and Location Support	$104.28	$30.00	$12.45	$72.45
Sales Portal	$5,000.00	$100.00	$45,000.00	$5,904.35
Provider Portal	$8,000.00	$2.50	$0.00	$4,696.52
Plan Comparison	$20.75	$125.00	$88.65	$61.44
Send Hotline Material	$0.60	$15.00	$12.45	$6.38
Benefit Summary Call	$0.00	$100.00	$0.00	$34.78
PAP Prescreening and Referrals	$62.00	$30.00	$89.65	$52.67
Prescription Triage	$68.00	$100.00	$12.45	$75.51
Prior Authorization	$68.00	$75.00	$111.82	$73.29
Injection Reminder	$21.00	$15.00	$12.45	$18.36
Analytics and Reporting	$110.00	$100.00	$135.00	$108.15
Sales Rep Hotline	$20.75	$15.00	$12.45	$18.21
Sample/Vouchers	$100.00	$30.00	$12.45	$69.94
CSR Training and On-boarding	$0.00	$100.00	$0.00	$34.78
Language Line	$0.00	$100.00	$1.00	$34.85
Telecommunications	$0.40	$100.00	$1.00	$35.08

95. Thus, whether outsourced or performed in-house, the tasks that must be completed before prescriptions are filled result in significant, tangible administrative costs to prescribers. These are direct costs that prescribers would have to incur in performing the tasks or in outsourcing the burdensome administrative tasks associated with support services.

96. Despite the significant costs associated with support services, prescribers are not allowed to charge the patient or their insurance provider for these tasks.[11] Thus, when an office-based prescriber receives payment for an office consultation, the payment is intended to compensate the prescriber for medical care given and administrative tasks associated with that patient's care.[12] These tasks include support services.

97. UCB was undoubtedly very aware of the time and cost associated with performing these services and chose to

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[11] For example, in Texas, "[p]roviders must certify that no charges beyond reimbursement paid under Texas Medicaid for covered services have been, or will be, billed to an eligible client." The Texas Medicaid Provider Procedures Manual makes clear to providers that "Federal regulations prohibit providers from charging clients a fee for completing or filing Medicaid claim forms" and notes that the "cost of claims filing is part of the usual and customary rate for doing business." Further, providers cannot charge "Texas Medicaid clients, their family, or the nursing facility for telephone calls, telephone consultations, or signing forms." Texas Medicaid Provider Procedures Manual § 1.6.9 (Dec. 2017), *available at* http://www.tmhp.com/Pages/Medicaid/Medicaid_Publications_Provider_manual.aspx (last accessed, Dec. 20, 2017).

[12] The technical term for an office visit is "evaluation and management services" or "E/M." In 2012, the most commonly billed Medicare physician service was the $70 "doctor office visit" for a 15-minute consultation, closely followed by the $100 "doctor office visit" for a 30-minute consultation. Medicare pays over $11 billion each year for E/M services alone. Medicaid and private insurers also pay billions each year.

incentivize prescribers to choose its drug over other drugs by assuming the responsibility and expense for these support services.

98. One of UCB's field reimbursement managers in Birmingham, Alabama, Chris Connell, provides reimbursement consultation for Cimzia to Rheumatology & GI practices and internal stakeholders including: benefits verification, claims filing & denials, prior authorization, coding, claims tracking & patient support services for accounts in AL, MS, LA, TN, GA, FL, KY.

99. UCB drug representatives' pitch to providers in this regard has essentially been as follows:

> *Dear Doctor: If you prescribe our drug (i.e., "recommend" the patient to use our drug), we will give you the services and resources of a full reimbursement support team to manage the process associated with prescribing the drug. This service will save you the cost and expenses normally associated with managing a patient's prescription and make your practice more profitable.*

100. This value proposition was a powerful tool in the hands of UCB's drug representatives and used to influence providers to recommend and prescribe UCB's Cimzia. UCB's drug representatives could offer a provider an "on call" reimbursement support team to manage the patient's UCB drug prescriptions.

Reimbursement support services became very much a part of the UCB drug representatives' collective sales pitch.

101. One former UCB sales representative who promoted and sold Cimzia described incentivizing prescribers as follows: "Doctor, we are going to work with you from the time you put a patient on a product, for the patient's setup and home injection, we are going to help you every step of the way. That will include a benefits investigation of the patient's insurance, co-pay support, patient assistance program for your indigent patients, appeals assistance, letters of medical necessity, nurse educator support, injection training, drug disposal, travel carry kits, nurse hotline. All those things are important so the physician understands that they are not going alone…with this prescription which is expensive, time consuming, and you know, in general is a pain in my rear end. So if you can help me with that, I'm interested in talking to you."

102. This same sales representative stated that offering these services "can be a real influencer on a prescriber."

103. That is, rather than promoting and marketing its drug based on patient outcomes and efficacy, UCB introduced an additional incentive to providers to recommend its drug to patients. UCB knew that this service would present a tangible value to the

providers. When that offer was accepted, the provider received the benefits of the reimbursement support service without actually having to pay for those services.

104. Most importantly, these services resulted in greater profit from each provider's evaluation and management unit charge. It was in this fashion, giving a provider free reimbursement support services, that UCB "eliminate[d] an expense that [the provider] would have otherwise incurred"[13] if the provider would have had to perform the tasks or pay to outsource these tasks associated with the prescription drug. Such "in kind" remuneration given to induce a recommendation for a UCB drug is an unlawful kickback under the AKS.

105. In 2012-2013, a case manager for RXCrossroads, Barbara Robinson, in Jeffersonville, Indiana provided full detailed benefit investigations for Cimizia, which included contacting insurance company, pharmacy benefit manager and specialty pharmacy; and checking eligibility deductible out of pocket expenses for patients enrolled in the Cimplicity Cimzia

[13] Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003) ("CPG") Section II (2), such service is a suspect remuneration as it "eliminate[d] an expense that the physician would have otherwise incurred (i.e., have independent value to the physician)".

106. Another case manager for RXCrossroads interviewed by Relator estimated that a normal benefit investigation could last anywhere from 45 minutes to two or three hours depending on hold times and knowledge of the insurance representative. Prior authorization for Cimzia could likewise take anywhere from 15 minutes to half an hour, while a coverage appeal could last from an hour to a span of several days. The case manager estimated that a prescriber's office would have to provide a salary of at least $40,000 per year just to provide these services. Another case manager estimated that prescriber's office would pay approximately $17 per hour to have someone handle these services in office.

107. A territory case manger for RXCrossroads, Jennifer Watson, in Louisville, Kentucky from 2011-2014 described her duties as follows:

> Managed a group of 5 people. Provided case management for key accounts within a territory. Managed Kentucky, Indiana, Ohio, and Michigan as well as managed key accounts in Washington, Tennessee, Florida, and Texas. Ensured that patients were on paid therapy, reported back to the territory sales representatives of patients that were on paid therapy. Assisted sales

> representatives in the field educating the physician offices on Cimzia therapy, how I could assist, how I could manage patient therapy, and initiate prior authorizations on their behalf. Followed up with patients, sales representatives, district managers, physician offices and specialty pharmacies to ensure therapy was being managed, shipments were being delivered, and that the territory goals were being met. Verified insurance coverage with patient's insurance carriers, obtained the coverage necessary, assisted with copay assistance as needed, combined together in a summary of benefits package that was submitted to the physicians office on behalf of patient. Assisted with quality assurance of peers, helping build account knowledge. Held the number one Crohn's district for 2 years in a row.

108. Defendants, thus, provided an extremely valuable benefit to the prescribers' offices that utilized their services for Cimzia as one RXCrossroads Cimzia case manager noted: "It is a very very big time saver, cost save for them because they can see multiple patients regarding their illnesses and their specialty that they're providing versus doing benefit investigation."

109. This same case manager further recognized: "We have more doctors prescribing the medication simply because they know that there are services that go hand in hand with it." She

confirmed that she saw an increase in prescriptions for Cimzia from a provider after utilizing the reimbursement support services.

110. Within the pharmaceutical industry, RXC openly promotes the nature of the services it offers to pharmaceutical companies and boasts that its services will increase a pharmaceutical company's drug sales. As one of the RXC Cimzia territory case managers confirmed, they provide a benefit to the doctors, which benefits the manufacturers.

111. Here, Defendants gave providers an *a la carte* single point of contact person to manage the UCB prescription process, which greatly reduced and/or eliminated the providers' overhead and expenses that would otherwise have been associated with any UCB prescription.

112. The reimbursement support services provided a significant value to providers because it eliminated the time and expense of determining and verifying patients' insurance benefits, determining whether a prescribed drug was on formulary and determining co-pays and deductibles. Reimbursement support services also saved providers' staff time because RXC would manage each step and communicate with the patient directly.

113. Through RXC, providers could also eliminate the

time and expense of appealing a denial of benefits and the cumbersome prior authorization process. Finally, providers no longer needed to manage a patient's call for refills or additional authorizations, as RXC managed this function as well.

114. By giving a provider reimbursement support services, Defendants gave a tangible "in kind" benefit to providers that greatly reduced, and in some instances eliminated, a provider's administrative costs related to prescribing UCB's drug, Cimzia, and thus induced providers to choose Cimzia over a competitor's drugs.

DAMAGES

115. Defendants' schemes and kickback violations resulted in the submission of numerous false claims to government programs.

116. As Defendants profited from the illegal schemes described herein, Medicare and Medicaid and other government health care programs were made to bear the costs. From 2011 to the present, Defendants' actions knowingly have caused pharmacies, Part D sponsors, Fiscal Intermediaries and others to submit millions of dollars in claims to Medicare and Medicaid for UCB's Cimzia that were provided to beneficiaries as a result of Defendants' illegal *quid pro quo* arrangements. Those false claims have caused

Medicare and Medicaid and other government health care programs to disburse tens of millions of dollars in reimbursements that should not have been paid.

117. Relators' investigation identified specific providers who were targeted with nurse educators and reimbursement support services in exchange for prescribing UCB's drug, Cimzia, and examples of claims submitted from these providers.

118. Exhibit A contains specific examples of Cimzia Medicare claims data corresponding to those individuals identified in Relators' investigation as being targeted with these *quid pro quo* services in exchange for Cimzia prescriptions.

119. These specific claims are linked to the Defendants' conduct alleged herein because each claim resulted from a prescription written by a prescriber who was offered and/or received unlawful remuneration under the nurse educator program. This unlawful remuneration saved the prescribers and their staff time, resources, and money that the prescriber would otherwise have had to incur to provide follow-up care and monitoring for patients treating with Cimzia.

120. These specific claims are further linked to the Defendants' conduct alleged herein because each claim resulted

from a prescription written by a prescriber who was offered and/or received unlawful remuneration under the support services program. This unlawful remuneration saved the prescribers and their staff time, resources, and money that the prescriber would otherwise have had to incur to perform administrative tasks necessary for the patients to receive treatment with Cimzia.

121. Given the breadth of Defendants' misconduct and the large volume of claims submitted to government programs, it is statistically impossible that Defendants' conduct did not result in the submission of false claims. Claims were submitted to federal and state healthcare programs, including Medicare and Medicaid, in most, if not all, states for Cimzia. Given that the marketing schemes described herein were actively promoted by UCB and widely used by prescribers, it is statistically impossible that claims for Cimzia were not submitted to Government programs.

122. Further, upon information and belief, Defendants were specifically targeting government programs. One former Cimzia sales representative mentioned UCB using data from its reimbursement support services program to identify the percentage of the Medicare market that they are capturing.

NO SAFE HARBOR

123. The safe harbor provided for personal services business arrangements under certain circumstances does not apply to any of Defendants' actions or arrangements pleaded in this Complaint for at least the following reasons: First, Defendants' agency agreement does not cover all of the services RXC provides and/or specify the services to be provided by RXC, or the agreement seeks to contract for the illegal activity described in this Complaint, rendering it void *ab initio*. Second, the compensation UCB paid to the RXC nurse educators was not set in advance and is determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other federal health care programs. Third, the services performed under the agreement involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law. Fourth, the aggregate services contracted for exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

SUMMARY

124. As detailed above, the Defendants are liable for damages based on the Government's payment of all claims submitted to federal health care programs for prescriptions written for UCB's Cimzia beginning from the time they began paying remuneration up and through the present because the claims were the result of recommendations induced, in whole or in part, by remuneration.

125. Compliance with the AKS is a precondition of payment by virtue of federal and state statutes, regulations, provider agreements, and contracts.

126. The certifications and attestations signed by physicians, pharmacies, PBMs and Part D sponsors certified compliance with the AKS. Kickbacks that were paid to and received by physicians and other health care professionals to recommend Cimzia as alleged herein rendered those certifications and attestations false. Those false statements were material to the false claims submitted for Cimzia.

127. Claims for UCB's Cimzia arising from the kickbacks expressly and impliedly misrepresent compliance with a material condition of payment, to wit, compliance with the AKS. Claims that

include items or services resulting from a violation of the AKS constitute false or fraudulent claims under the AKS. 42 U.S.C. §§ 1320a-7a(7) and 1320a-7b(b) and 1320a-7b(g).

128. By providing remuneration to physicians and other health care professionals, UCB intended to induce those physicians and other health care professionals to recommend and/or prescribe UCB's Cimzia.

129. It was reasonably foreseeable that some of those prescriptions would be for federal health care program beneficiaries and that claims for those prescriptions would be submitted to federal health care programs. Thousands of such prescriptions or claims based on such prescriptions were, in fact, submitted to and paid for by federal health care programs.

COUNTS

FIRST COUNT – AGAINST ALL DEFENDANTS
For Violations of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

130. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

131. Relator seeks relief against Defendants under Section 3729(a)(1)(A) of the FCA, 31 U.S.C. § 3729(a)(1)(A).

132. As a result of UCB's offering or paying, and UCB's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend the purchasing or ordering of UCB's drug, Cimzia, in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants caused false and fraudulent claims for payment to be presented to federal health care programs.

133. Accordingly, Defendants knowingly caused to be presented false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

134. By reason of the false or fraudulent claims that Defendants knowingly caused to be presented to federal health care programs, the United States has been damaged in a substantial amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

SECOND COUNT – AGAINST ALL DEFENDANTS
For Violations of the False Claims Act:
Use of False Statements (31 U.S.C. § 3729(a)(1)(B))

135. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

136. Relator seeks relief against Defendants under Section 3729(a)(1)(B) of the FCA, 31 U.S.C. § 3729(a)(1)(B).

137. As a result of UCB's offering or paying, and UCB's co-Defendants, physicians, and other health care professionals soliciting or receiving, kickbacks to purchase, order, or recommend purchasing or ordering UCB's drug, Cimzia, in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), Defendants knowingly caused pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others to make false records or statements that were material to getting false or fraudulent claims paid by federal health care programs.

138. More specifically, the pharmacies, PBMs, Part D sponsors, fiscal intermediaries, and others, falsely certified, and/or represented that the reimbursements they sought for UCB's drug, Cimzia, were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including but not limited to the AKS. Those false certifications, statements, or

representations caused federal health care programs to pay out sums that would not have been paid if those programs had been made aware of the falsity of the certifications, statements, or representations.

139. Accordingly, Defendants caused the use of false records or statements material to false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(B).

140. By reason of these false records or statements, the United States has been damaged in a substantial amount to be determined at trial, and is entitled to treble damages plus a monetary civil penalty for each false record or statement.

THIRD COUNT – AGAINST ALL DEFENDANTS
For Violations of the False Claims Act:
Conspiring to Violate the False Claims Act (31 U.S.C. § 3729(a)(1)(C))

141. Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

142. Relator seeks relief against Defendants under Section 3729(a)(1)(C) of the FCA, 31 U.S.C. § 3729(a)(1)(C).

143. As set forth above, UCB conspired with UCB's co-Defendants, physicians, and other health care professionals to offer or pay kickbacks in exchange for, or to induce them to purchase,

order, or recommend the purchasing or ordering of UCB's drug, Cimzia, in violation of the federal AKS, 42 U.S.C. § 1320a-7b(b)(1) and (b)(2), thereby causing false and fraudulent claims to be presented to federal health care programs seeking reimbursement for UCB's drug, Cimzia, dispensed in connection with the kickback scheme.

144. Accordingly, Defendants conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C).

145. By reason of the Defendants' conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount to be determined at trial, and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

FOURTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the California False Claims Act
Cal. Gov't Code §§ 12650 – 12656

146. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §§ 12650 – 12656. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

147. Defendants violated the California False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of California as described herein.

148. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of California.

149. The State of California, unaware of the false or fraudulent nature of these claims, paid such claims which the State of California would not otherwise have paid.

150. By reason of these payments, the State of California has been damaged, and continues to be damaged, in a substantial amount.

FIFTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Colorado Medicaid False Claims Act
Col. Rev. Stat. Ann. §§ 25.5-4-303.5 – 25.5-4-310

151. This is a claim for treble damages and civil penalties under the Colorado Medicaid False Claims Act, Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 – 25.5-4-310. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

152. Defendants violated the Colorado Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Colorado, as described herein.

153. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Colorado.

154. The State of Colorado, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Colorado would not otherwise have paid.

155. By reason of these payments, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount.

SIXTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Connecticut False Claims And Other Prohibited Acts Under State-Administered Health or Human Services Act ("Connecticut False Claims Act")
Conn. Gen. Stat. Ann. §§ 4-274-4-289.

156. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. Ann. §§ 4-274-4-289. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

157. Defendants violated the Connecticut False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Connecticut, as described herein.

158. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Connecticut.

159. The State of Connecticut, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Connecticut would not otherwise have paid.

160. By reason of these payments, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount.

SEVENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Delaware False Claims and Reporting Act
Del. Code Ann. Tit. 6, §§ 1201 – 1211

161. This is a claim for treble damages and civil penalties under the Delaware False Claims and Reporting Act, Del. Code Ann. Tit. 6, §§ 1201 – 1211. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

162. Defendants violated the Delaware False Claims and Reporting Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Delaware, as described herein.

163. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Delaware.

164. The State of Delaware, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Delaware would not otherwise have paid.

165. By reason of these payments, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount.

EIGHTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act of 2012
D.C. Code Ann. §§ 2-381.01 – 2-381.10

166. This is a claim for treble damages and civil penalties under the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act, D.C. Code Ann. §§ 2-381.01 – 2-381.10. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

167. Defendants violated the District of Columbia Medicaid Fraud Enforcement and Recovery Amendment Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the District of Columbia, as described herein.

168. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the District of Columbia.

169. The District of Columbia, unaware of the false or fraudulent nature of these claims, paid such claims which the District of Columbia would not otherwise have paid.

170. By reason of these payments, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount.

NINTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Florida False Claims Act
Fla. Stat. Ann. §§ 68.081 – 68.092

171. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081 – 68.092. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

172. Defendants violated the Florida False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Florida as described herein.

173. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Florida.

174. The State of Florida, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Florida would not otherwise have paid.

175. By reason of these payments, the State of Florida has been damaged, and continues to be damaged, in a substantial amount.

TENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Georgia False Medicaid Claims Act
Ga. Code Ann. §§ 49-4-168 – 49-4-168.6

176. This is a claim for treble damages and civil penalties under Georgia False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 – 49-4-168.6. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

177. Defendants violated the Georgia State False Medicaid Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Georgia, as described herein.

178. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Georgia.

179. The State of Georgia, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Georgia would not otherwise have paid.

180. By reason of these payments, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount.

ELEVENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Hawaii False Claims Act for False Claims to the State
Haw. Rev. Stat. §§ 661-21 – 661-31

181. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act for False Claims to the State, Haw. Rev. Stat. §§ 661-21 – 661-31. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

182. Defendants violated the Hawaii False Claims Acts for False Claims to the State by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Hawaii, as described herein.

183. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Hawaii.

184. The State of Hawaii, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Hawaii would not otherwise have paid.

185. By reason of these payments, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount.

TWELFTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Illinois False Claims Act
740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8

186. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. Ann. §§ 175/1 – 175/8. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

187. Defendants violated the Illinois False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Illinois, as described herein.

188. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois.

189. The State of Illinois, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Illinois would not otherwise have paid.

190. By reason of these payments, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount.

THIRTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Indiana False Claims and Whistleblowers Protection Act
Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18

191. This is a claim for treble damages and civil penalties under the Indiana False Claims and Whistleblowers Protection Act, Ind. Code Ann. §§ 5-11-5.5-1 – 5-11-5.5-18. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

192. Defendants violated the Indiana False Claims and Whistleblowers Protection Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Indiana, as described herein.

193. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a

false record or statement to get a false or fraudulent claim paid or approved by the State of Indiana.

194. The State of Indiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Indiana would not otherwise have paid.

195. By reason of these payments, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount.

FOURTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Iowa False Claims Act
Iowa Code Ann. §§ 685.1 – 685.7

196. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code Ann. §§ 685.1- 685.7. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

197. Defendants violated the Iowa False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Iowa, as described herein.

198. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a

false record or statement to get a false or fraudulent claim paid or approved by the State of Iowa.

199. The State of Iowa, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Iowa would not otherwise have paid.

200. By reason of these payments, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount.

FIFTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §§ 437.1 – 440.16

201. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 437.1 – 440.16. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

202. Defendants violated the Louisiana Medical Assistance Programs Integrity Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Louisiana, as described herein.

203. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Louisiana.

204. The State of Louisiana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Louisiana would not otherwise have paid.

205. By reason of these payments, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount.

SIXTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Massachusetts False Claims Law
Mass. Gen. Laws Ann. Ch. 12 §§ 5A – 5O

206. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Law, Mass. Gen. Laws Ann. Ch. 12, §§ 5A – 5O. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

207. Defendants violated the Massachusetts False Claims Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Massachusetts, as described herein.

208. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Massachusetts.

209. The Commonwealth of Massachusetts, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Massachusetts would not otherwise have paid.

210. By reason of these payments, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount.

SEVENTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Michigan Medicaid False Claims Act
Mich. Comp. Laws Ann. §§ 400.601 – 400.615

211. This is a claim for treble damages and civil penalties under the Michigan Medicaid False Claims Act, Mich. Comp. Laws Ann. §§ 400.601 – 400.615. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

212. Defendants violated the Michigan Medicaid False Claims Act by engaging in the fraudulent and illegal practices

described herein, including knowingly causing false claims to be presented to the State of Michigan, as described herein.

213. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Michigan.

214. The State of Michigan, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Michigan would not otherwise have paid.

215. By reason of these payments, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount.

EIGHTEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Minnesota False Claims Act
Minn. Stat. Ann. §§ 15C.01 – 15C.16

216. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. Ann. §§ 15C.01 – 15C.16. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

217. Defendants violated the Minnesota False Claims Act by engaging in the fraudulent and illegal practices described herein,

including knowingly causing false claims to be presented to the State of Minnesota, as described herein.

218. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Minnesota.

219. The State of Minnesota, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Minnesota would not otherwise have paid.

220. By reason of these payments, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount.

NINETEENTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Montana False Claims Act
Mont. Code Ann. §§ 17-8-401 – 17-8-416

221. This is a claim for treble damages and civil penalties under Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 – 17-8-416. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

222. Defendants violated the Montana False Claims Act by engaging in the fraudulent and illegal practices described herein,

including knowingly causing false claims to be presented to the State of Montana, as described herein.

223. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Montana.

224. The State of Montana, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Montana would not otherwise have paid.

225. By reason of these payments, the State of Montana has been damaged, and continues to be damaged, in a substantial amount.

TWENTIETH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Nevada Submission of False Claims to State or Local Government Act
Nev. Rev. Stat. Ann. §§ 357.010 – 357.250

226. This is a claim for treble damages and civil penalties under the Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. Ann. §§ 357.010 – 357.250. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

227. Defendants violated the Nevada Submission of False Claims to State or Local Government Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Nevada, as described herein.

228. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Nevada.

229. The State of Nevada, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Nevada would not otherwise have paid.

230. By reason of these payments, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FIRST COUNT– AGAINST ALL DEFENDANTS
For Violations of the New Jersey False Claims Act
N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18

231. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 – 2A:32C-18. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

232. Defendants violated the New Jersey False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Jersey, as described herein.

233. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Jersey.

234. The State of New Jersey, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Jersey would not otherwise have paid.

235. By reason of these payments, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SECOND COUNT– AGAINST ALL DEFENDANTS
For Violations of the New Mexico Medicaid False Claims Act N.M. Stat. Ann. §§ 27-14-1 – 27-14-15

236. This is a claim for treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 – 27-14-15. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

237. Defendants violated the New Mexico Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

238. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

239. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

240. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-THIRD COUNT– AGAINST ALL DEFENDANTS
For Violations of the New Mexico Fraud Against Taxpayers Act
N.M. Stat. Ann. §§ 44-9-1 – 44-9-14.

241. This is a claim for treble damages and civil penalties under the New Mexico Fraud Against Taxpayers False Claims Act, N.M. Stat. Ann. §§ 44-9-1 – 44-9-14. Relator re-alleges and

incorporates the allegations in the preceding paragraphs as if set forth fully herein.

242. Defendants violated the New Mexico Fraud Against Taxpayers False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New Mexico, as described herein.

243. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New Mexico.

244. The State of New Mexico, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New Mexico would not otherwise have paid.

245. By reason of these payments, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FOURTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the New York False Claims Act
N.Y. Fin. Law §§ 187 – 194

246. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. Fin. Law §§ 187 – 194. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

247. Defendants violated the New York False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of New York, as described herein.

248. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of New York.

249. The State of New York, unaware of the false or fraudulent nature of these claims, paid such claims which the State of New York would not otherwise have paid.

250. By reason of these payments, the State of New York has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-FIFTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the North Carolina False Claims Act
N.C. Gen. Stat. Ann. §§ 1-605 – 1-618

251. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. Ann. §§ 1-605 – 1-618. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

252. Defendants violated the North Carolina False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of North Carolina, as described herein.

253. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of North Carolina.

254. The State of North Carolina, unaware of the false or fraudulent nature of these claims, paid such claims which the State of North Carolina would not otherwise have paid.

255. By reason of these payments, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SIXTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Oklahoma Medicaid False Claims Act
Okla. Stat. Ann. Tit. 63, §§ 5053 – 5054

256. This is a claim for treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Okla. Stat. Ann. Tit. 63, §§ 5053 – 5054. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

257. Defendants violated the Oklahoma Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Oklahoma, as described herein.

258. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Oklahoma.

259. The State of Oklahoma, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Oklahoma would not otherwise have paid.

260. By reason of these payments, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-SEVENTH COUNT– AGAINST ALL DEFENDANTS

For Violations of the Rhode Island State False Claims Act

R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9

261. This is a claim for treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws Ann. §§ 9-1.1-1 – 9-1.1-9. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

262. Defendants violated the Rhode Island State False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Rhode Island, as described herein.

263. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Rhode Island.

264. The State of Rhode Island, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Rhode Island would not otherwise have paid.

265. By reason of these payments, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-EIGHTH COUNT– AGAINST ALL DEFENDANTS

For Violations of the Tennessee False Claims Act Tenn. Code Ann. §§ 4-18-101 – 4-18-108 And For Violations of the Tennessee Medicaid False Claims Act Tenn. Code Ann. §§ 71-5-181 – 71-5-185

266. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 – 4-18-108 and the Tennessee Medicaid False Claims Act, Tenn. Code. Ann. §§ 71-5-181 – 71-5-185. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

267. Defendants violated the Tennessee False Claims Act and the Tennessee Medicaid False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Tennessee, as described herein.

268. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Tennessee.

269. The State of Tennessee, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Tennessee would not otherwise have paid.

270. By reason of these payments, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount.

TWENTY-NINTH COUNT– AGAINST ALL DEFENDANTS
For Violations of the Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132

271. This is a claim for treble damages and civil penalties under the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 – 36.132. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

272. Defendants violated the Texas Medicaid Fraud Prevention Law by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Texas, as described herein.

273. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a

false record or statement to get a false or fraudulent claim paid or approved by the State of Texas.

274. The State of Texas, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Texas would not otherwise have paid.

275. By reason of these payments, the State of Texas has been damaged, and continues to be damaged, in a substantial amount.

THIRTIETH– AGAINST ALL DEFENDANTS
For Violations of the Virginia Fraud Against Taxpayers Act
Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19

276. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 – 8.01-216.19. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

277. Defendants violated the Virginia Fraud Against Taxpayers Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the Commonwealth of Virginia, as described herein.

278. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a

false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth of Virginia.

279. The Commonwealth of Virginia, unaware of the false or fraudulent nature of these claims, paid such claims which the Commonwealth of Virginia would not otherwise have paid.

280. By reason of these payments, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount.

THIRTY-FIRST COUNT– AGAINST ALL DEFENDANTS
For Violations of the Washington Medicaid Fraud False Claims Act
Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130

281. This is a claim for treble damages and civil penalties under the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code Ann. §§ 74.66.005 – 74.66.130. Relator re-alleges and incorporates the allegations in the preceding paragraphs as if set forth fully herein.

282. Defendants violated the Washington Medicaid Fraud False Claims Act by engaging in the fraudulent and illegal practices described herein, including knowingly causing false claims to be presented to the State of Washington, as described herein.

283. As a result of the misconduct alleged herein, Defendants knowingly made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Washington.

284. The State of Washington, unaware of the false or fraudulent nature of these claims, paid such claims which the State of Washington would not otherwise have paid.

285. By reason of these payments, the State of Washington has been damaged, and continues to be damaged, in a substantial amount.

PRAYER FOR RELIEF

WHEREFORE, Relator requests that judgment be entered against Defendants as follows:

(a) treble the Government's damages in an amount determined at trial, plus the maximum statutorily-allowed penalty for each false claim submitted in violation of the FCA or State statute set forth above;

(b) the applicable administrative civil penalties for each violation of the AKS and State-equivalent statute, as well as an assessment of not more than three times the amount of remuneration offered, paid, solicited or received, without regard to whether a

portion of that amount was offered, paid or received for a lawful purpose;

(c) an award of costs and the maximum Relator award allowed pursuant to the FCA and State statutes set forth above; and

(d) such further relief as is proper.

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38, Relator hereby demands trial by jury.

Dated this the 14th day of May, 2019.

/s/ C. Lance Gould
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CERTIFICATE OF SERVICE

I certify that I caused this document filed through the ECF system to be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants.

Dated: May 14, 2019 By: /s/ C. Lance Gould
C. LANCE GOULD